



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (kml)
FOLDER: K140194 - 725 pages
COMPANY: NAVILYST MEDICAL, INC. (NAVIMEDI)
PRODUCT: SYRINGE, PISTON (FMF)
SUMMARY: Product: NAMIC RCS SYRINGE

DATE REQUESTED: Dec 21, 2015

DATE PRINTED: Dec 21, 2015

Note: Printed



Navilyst Medical, Inc.
 NAMIC RCS, Abbreviated 510(k)
 January 24, 2014

APR 14 2014

510(k) SUMMARY FOR THE NAMIC RCS

Date prepared: January 24, 2014

A. Sponsor

Navilyst Medical, Inc
 26 Forest Street
 Marlborough, MA 01752

B. Contact

Brandon M. Brackett
 Specialist, Global Regulatory Affairs
 508-658-7984

OR Wanda Carpinella
 Director of Global Regulatory Affairs
 508-658-7929

C. Device Name

Trade Name	NAMIC RCS
Common/Usual name:	Piston Syringe
Classification Name:	Syringe, Piston (21CFR§880.5860, Class II)
Classification Panel:	General Hospital

D. Predicate Device(s)

Common/Usual name:	Piston Syringe
Classification Name	Syringe, Piston - 21CFR§880.5860, Class II
Classification Panel:	General Hospital
Premarket Notification	K113198, K875196, K873955

E. Device Description

Intended Use

The NAMIC RCS is intended to be used for the intra-arterial or intra-venous administration of radiographic contrast media and saline solutions during an angiographic procedure.

F. Summary of Similarities and Differences in Technological Characteristics and Performance

The proposed NAMIC RCS syringes incorporate similar materials, design, components, technological characteristics, and intended us as the predicate syringes.

G. Performance Data

The NAMIC RCS is substantially equivalent to the predicate devices based on comparison of technological characteristics and the results of non-clinical tests which included the performance evaluation conducted in accordance with the following FDA guidance documents, international standards, and testing which included:

- FDA's "Guidance on the Content of Premarket Notification 510(k) Submissions for Piston Syringes dated April 1993"
- ISO 7886-1:1997 "Sterile Hypodermic Syringes for Single Use – Part 1: Syringes for Manual Use"
- ISO 594-2:1998 "Conical Fittings 6% (Luer) Taper for Syringes, Needles, Certain Other Medical Equipment – Part 2: Lock Fittings"

H. Conclusion

The results of the non-clinical testing and a comparison of similarities and differences demonstrate that the proposed and predicate devices are substantially equivalent.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 14, 2014

Navilyst Medical, Inc.
Brandon M. Brackett
Global Regulatory Affairs Specialist
26 Forest Street
Marlborough, MA 01752

Re: K140194
Trade/Device Name: NAMIC RCS
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF
Dated: January 24, 2014
Received: January 27, 2014

Dear Mr. Brackett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

Page 2 – Mr. Brackett

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K140194

Device Name
NAMIC RCS

Indications for Use (Describe)

The NAMIC RCS is intended to be used for the intra-arterial or intra-venous administration of radiographic contrast media and saline solutions during an angiographic procedure.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Digitally signed by Richard C. Chapman
Date: 2014.04.14 08:59:45 -04'00'

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26 Forest Street
Marlborough, MA 01752
508.658.7990 Tel

www.navilystmedical.com

FDA CDRH DMC

JAN 27 2014

Received

January 24, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center - W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-002

Subject: Premarket Notification – Abbreviated 510(k) for proposed **NAMIC RCS**

Dear Sir/Madam:

According to Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 21 CFR §807 Subpart E, Navilyst Medical, Inc. (NMI) hereby submits one copy (one original paper copy and one exact duplicate copy in an electronic form) of this Abbreviated 510(k) Premarket Notification for the proposed **NAMIC RCS**. For ease of FDA review and based on prior FDA requests, we've provided an additional eCopy.

The purpose of this Abbreviated 510(k) is to achieve FDA clearance to introduce into commercial distribution an extension to our current syringe offerings, consisting of a range of sizes and colors. Design verification and validation activities have been completed, and data in regards to performance, shelf-life, biocompatibility, sterilization, and packaging have been provided to support the safety and effectiveness of the proposed device and to demonstrate substantial equivalence to the predicates.

The Abbreviated 510(k) approach was selected because an FDA guidance document exists ("*Guidance on the Content of Premarket Notification [510(K)] Submissions for Piston Syringes*") and there are FDA-recognized standards associated with this type of device, of which the device conforms with.

The predicate 510(k)'s to the proposed device include **K113198**, **K875196**, and **K873955** and there was no pre-submission correspondence (including Pre-Submission Requests) between Navilyst Medical, Inc. and the Agency related to this submission.

Navilyst Medical, Inc. considers the content of this letter and the existence of the 510(k) to be confidential commercial information and exempt from public disclosure; and therefore, requests that FDA does not disclose the existence or content of this 510(k) submission or this letter. Should you have any questions regarding this submission please contact me directly at 508-658-7984, or Ms. Wanda Carpinella, Director of Global Regulatory Affairs at 508-658-7929.

Sincerely,

Brandon M. Brackett
Specialist, Global Regulatory Affairs
Navilyst Medical, Inc.
Phone: 508-658-7984
Fax: 508-658-7976
E-mail: brandon.brackett@navilyst.com

Note: the eCopy is an exact duplicate of the paper copy.

K140194



Premarket Notification – Abbreviated 510(k)

NAMIC RCS

General Hospital

Date: January 24, 2014

Navilyst Medical, Inc.
26 Forest Street
Marlborough, MA 01752

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INTRODUCTORY INFORMATION

PREMARKET NOTIFICATION 510(K) CHECKLIST FOR ACCEPTANCE DECISION AND REQUIRED INFORMATION

1. Critical Elements:

The proposed peripherally inserted central catheter, as defined in Section 201 of the Federal Food, Drug, and cosmetic Act, as Amended (the Act), is not exempt from the 510(k) requirements, by regulation or by policy, and is subject to review by CDRH.

A. Has the device been the subject of a previous NSE decision? NO

2. Required Information (under Sections 510(k), 513 (f), and 512 (i) of the Act, and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations):

a.	Device trade or proprietary name:	NAMIC RCS
b.	Device common usual name, or classification:	Syringe, Piston
c.	Establishment registration number: Owner/Operator number:	3006716497 10024617
d.	Class into which the device is classified (21 CFR Parts 862 to 892):	Class II; 21 CFR 880.5860 ProCode: FMF
e.	Classification Panel:	General Hospital Device Panel
f.	Action taken to comply with Section 514 of the Act:	Navilyst Medical, Inc. is not aware of any specific performance standards addressing this device for compliance with Section 514 of The Act.
g.	Proposed labels, instructions for use: (which describes the device, its intended use, and directions for use):	Section 13
h.	510(k) Summary:	Section 5
i.	For Class III devices only, a Class III certification and a Class III Summary:	Section 7 Not Applicable to Device
j.	Photographs of the device:	Section 10
k.	Engineering drawings for the device with dimensions and tolerances:	Section 10
l.	Marketed device(s) to which substantial equivalence is claimed including labeling and description of device:	Sections 5, 11, and 13
m.	Statement of similarities and/or differences from the marketed device(s):	Section 11
n.	Data to show consequences and effects of modified device:	Section 12

3. Additional Information that is necessary under 21 CFR 807.87 (h):

a.	Submitter's name and address:	Navilyst Medical, Inc. 26 Forest Street Marlborough, MA 01752
	Owner Operator Number:	10024617
b.	Contact Person(s), telephone, fax:	Brandon M. Brackett Specialist, Global Regulatory Affairs Navilyst Medical, Inc. Phone: 508-658-7984 Fax: 508-658-7976 Email: brandon.brackett@navilyst.com OR: Wanda Carpinella Director, Global Regulatory Affairs Navilyst Medical, Inc. Phone: 508-658-7929 Fax: 508-658-7976 Email: wanda.carpinella@navilyst.com
c.	Representative/Consultant, if applicable:	Not Applicable
d.	Table of Contents with Pagination:	Table of Contents
e.	Manufacturing Facility/Facilities Name and Address:	Navilyst Medical, Inc 10 Glens Falls Technical Park Glens Falls, NY 12801 USA
	Establishment Registration Number:	1317056
f.	Sterilization Site(s) Name and Address:	(b) (4)

Abbreviated 510(k) Acceptance Check List
Completed and Created by Navilyst Medical, Inc. to aide reviewers
 Based on CDRH “*Refuse to Accept Policy for 510(k)s –*
Guidance for Industry and Food and Drug Administration Staff”, 31 Dec. 2012
 NAMIC RCS

		Y	N/A	N
Preliminary Questions				
1.	Is the product a device (per section 201(h) of the FD&S Act) or a combination product (per 21 CFR 3.2 (e)) with a device constituent part subject to review in a 510(k)?	X		
Comment: Yes.				
2.	Is the application with the appropriate Center?	X		
Comment: Yes.				
3.	If a Request for Designation (RFD) was a submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD# and confirm the following: a) Is the device or combination the same (e.g., design, formulation) as the predicate in the RFD submission? b) Are there indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?		X	
Comment: Not Applicable.				
4.(1)	Is the device type eligible for a 510(k) submission?	X		
Comment: Yes.				
4. (2)	Is there a pending PMA for the same device with the same indications for use?		X	
Comment: Not Applicable.				
5.	If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?		X	
Comment: Not Applicable.				

		Y	N/A	N
Abbreviated 510(k) Criteria				
1.	Submission relies on a device-specific guidance document, other than a special controls guidance document, and a summary report is provided that:	X		
	a. Includes a description of adherence to the relevant guidance document to support substantial equivalence	X		
	b. Includes a description of how the guidance document was used to satisfy the requirements of 21 CFR 807.87 (e.g., data to support substantial equivalence) and lists any deviations	X		
Comment: A Summary report identifying compliance to the guidance document is provided.				
2.	Submission relies on a special control(s), either in a device-specific regulation or special controls document, as defined in Section 513(a)(1)(B) of the FD&C Act, to demonstrate substantial equivalence and a summary report is provided that:		X	
	a. Includes a description of adherence to the special control(s) to support substantial equivalence			
	b. Includes a description of how the special control(s) was used to satisfy the requirements of 21 CFR 807.87 (e.g., data to support substantial equivalence) and lists any deviations			

		Y	N/A	N
	Comment: Not Applicable.			
3.	Submission relies on device-specific standard(s) (See section 514(c)).	X		
	For each cited standard:			
	a. Submission includes: - the device specific conformity statement as specified in device-specific guidance document (e.g., latex condoms) or - a declaration for conformity to the device specific standard OR the items below for use of FDA-recognized consensus standards	X		
	i. An identification of the applicable FDA-recognized consensus standards (full citation including version number)	X		
	ii. An identification, for each consensus standard, of any adaptations of the standard for evaluation of the device under review (e.g., an identification of an alternative series of tests that were performed)	X		
	iii. An identification, for each consensus standard, of any items (e.g., normative requirements of the standard) applicable to your device	X		
	iv. A specification of any deviations from each applicable standard (e.g., deviations from international standards which are necessary to meet U.S. infrastructure conventions such as the National Electrical Code (ANSI/NFPA 70))	X		
	v. A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification for the applicability of the test results in these areas of differences.	X		
	Comment: Declarations of Conformity and 510(k) Standards Data Report forms provided in Section 18.			

		Y	N/A	N
	Organizational Elements			
	a. Submission contains Table of Contents	X		
	b. Each section is labeled	X		
	c. All pages of the submission are numbered	X		
	d. Type of 510(k) is identified– traditional, abbreviated, or special	X		
	Comment: Type of 510(k) is Abbreviated (see Section 3).			

Elements of a Complete Submission (21 CFR 807.87 unless otherwise indicated)				
A.	Administrative			
1.	All content used to support the submission is written in English	X		
2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or in 510(k) cover letter):	X		
	a. Device trade name or proprietary name	X		
	b. Device common name	X		
	c. Device class and panel or	X		

		Y	N/A	N
	Classification regulation or Statement that device has not been classified with rationale for that conclusion			
	Comment: See Section 2.			
3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also and 801.109)	X		
	Comment: See Section 4.			
4.	Submission contains 510(k) Summary or 510(k) Statement	X		
	a. Summary contains all elements per 21 CFR 807.92	X		
	b. Statement contains all elements per 21 CFR 807.93		X	
	Comment: See Section 5.			
5.	Submission contains <u>signed</u> Truthful and Accuracy Statement per 21 CFR 807.87(k)	X		
	Comment: See Section 6.			
6.	Submission contains signed Class III Summary and Certification		X	
	Comment: Not Applicable – Device is Class II.			
7.	Submission contains clinical data		X	
	a. Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each clinical study included in the submission.		X	
	b. Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission.		X	
	Comment: Not Applicable			
8.	If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (FDA Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	X		
	Comment: See Section 18.			
9.	The submission identifies related submissions for the same device which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre- Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	X		
	a. If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed.		X	
	Comment: See Section 2.			
B. Device Description				
10.	a. If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.		X	
	b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative	X		

		Y	N/A	N
	approach.			
	Comment: See Section 10.			
11.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:	X		
	a. A description of the principle of operation and mechanism of action for achieving the intended effect.	X		
	b. A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other interface compatible devices; and/or how the device interacts with the patient.	X		
	c. A list and description of each device for which clearance is requested.	X		
	Comment: See Sections 4, 9, and 10.			
12.	Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X		
	Comment: See Section 10.			
13.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system			
	a. Submission includes a list of all components and accessories to be marketed with the subject device.	X		
	b. Submission includes a description (as detailed in item #11.a. and b. and 12 above) of each component or accessory.	X		
	c. A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.	X		
	Comment: See Section 10.			
C.	Substantial Equivalence Discussion			
14.	Submitter has identified a predicate(s) device	X		
	a. Predicate's 510(k) number, trade name, and model number (if applicable) provided.	X		
	b. The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	X		
	Comment: See Sections 5 and 11.			
15.	Submission includes a comparison of the following for the predicate(s) and subject device	X		
	a. Indications for use	X		
	b. Technology, including features, materials, and principles of operation	X		
	Comment: See Section 11.			
16.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate) affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(1)(A) of the FD&C Act)	X		
	Comment: See Section 11.			
D.	Proposed Labeling (see also 21 CFR part 801)			
	If a vitro diagnostic (IVD) device, criteria 17, 18, and 19 may be		X	

		Y	N/A	N
	omitted			
17.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and directions for use.	X		
	a. Indications for use are stated in the labeling and are identical to Indications for Use form and 510(k) summary (if 510(k) Summary provided.)	X		
	b. Submission includes directions for use that <ul style="list-style-type: none"> - Include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) AND - Includes directions for layperson (see 21CFR 801.5) OR submission states that the device qualifies for exemption 21 21 CFR 801 Subpart D 	X		
	Comment: See Section 13 and Attachment 1.			
18.	If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol	X		
	Comment: See Section 13 and Attachment 1.			
19.	General labeling provisions			
	a. Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	X		
	b. Labeling includes device common or usual name (21 CFR 801.61)	X		
	Comment: See Section 13 and Attachment 1.			
20.	a. If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.		X	
	b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.	X		
	c. If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set for in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.		X	
	Comment: See Section 13 and Attachment 1.			
21.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.		X	
E.	Sterilization			
	If in vitro diagnostic (IVD) device, select N/A. The criteria in the section will be omitted from the checklist if N/A is selected.			
	Submission states that the device and/or accessories are (one of the below must be checked) <ul style="list-style-type: none"> <input checked="" type="checkbox"/> provided sterile <input type="checkbox"/> provided non-sterile but sterilized by the end user <input type="checkbox"/> non-sterile when used 	X		
	Comment: See Section 14.			

		Y	N/A	N
22.	Assessment of the need for sterilization information			
	a. Identification of device, and/or accessories, and/or components that are provided sterile.	X		
	b. Identification of device, and/or accessories, and/or components that are end user sterilized.		X	
	c. Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.		X	
	Comment: See Section 14.			
23.	If the device, and/or accessory, and/or component is provided sterile:			
	a. Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	X		
	b. A description of the method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method.	X		
	c. For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	X		
	d. Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	X		
	e. Sterility Assurance Level (SAL) stated	X		
	Comment: See Sections 10 and 14.			
24.	If the device, and/or accessory, and/or component is end user sterilized:		X	
	a. Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)			
	b. A description of the method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method.			
	c. Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)			
	d. Submission includes sterilization instructions for end user			
25.	a. If there are requirements regarding sterility controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.		X	
	b. If there is a device-specific guidance other than a special controls guidance document applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.		X	
	c. If there is a special controls guidance document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document uses alternative		X	

		Y	N/A	N
	mitigation measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			
F. Shelf Life				
26.	Proposed shelf life/expiration date stated	X		
	Comment: See Section 14.			
27.	For sterile device, submission included summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life, or a rationale for why testing to establish shelf life is not applicable.	X		
	Comment: See Section 14.			
28.	Submission includes summary of methods used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the predicate, or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	X		
	Comment: See Section 12.			
G. Biocompatibility				
	If a vitro diagnostic (IVD) device, select N/A. The criteria in the section will be omitted from the checklist if N/A is selected.		X	
	Submission states that there: <input checked="" type="checkbox"/> are <input type="checkbox"/> are not direct or indirect (e.g., through infusion) patient-contacting components.			
	Comment: See Section 15			
29.	Submission includes a list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	X		
	Comment: See Section 15			
30.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	X		
	Comment: See Section 15			
31.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria. And results provided for each completed test, OR A statement that the biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X		
	Comment: See Section 15 and Attachment 2.			
H. Software				
	Submission states that the device: <input type="checkbox"/> does <input checked="" type="checkbox"/> does not contain software/firmware.			
	Comment: See Section 16			
32.	Submission includes a statement of software level of concern and rationale for the software level of concern.			
	Comment: Not Applicable			

		Y	N/A	N
33.	All applicable software documentation provided based on the level of concern identified by the submitter, as described in Guidance for the Content of premarket Submissions for Software Contained in Medical Devices , or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).			
Comment: Not Applicable				
I. EMC and Electrical Safety				
	Submission states that the device: <input type="checkbox"/> does <input checked="" type="checkbox"/> does not require EMC and Electrical Safety evaluation	X		
34.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).		X	
Comment: Not Applicable (See Section 17)				
35.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).			
Comment: Not Applicable (See Section 17)				
J. Performance Data – General If in vitro diagnostic (IVD) device, select “N/A.” The criteria in this section will be omitted from the checklist if “N/A” is selected. Performance data criteria relating to IVD devices will be addressed in Section K.				
36.	Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.	X		
Comment: See Section 12				
37.	a. If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.		X	
	b. If there is a device-specific guidance, other than a special controls	X		

		Y	N/A	N
	guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach			
	c. If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.		X	
	Comment: See Section 12			
38.	If literature is referenced in the submission, submission includes:			
	a. Legible reprints or a summary table of each article		X	
	b. Discussion of how each article is applicable to support substantial equivalence of the subject device to the predicate.		X	
	Comment: N/A.			
39.	For each completed nonclinical (i.e., animal) study conducted		X	
	a. Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120			
	b. Submission includes final study report which includes all elements outlined in 21 CFR 58.185			
	c. Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.			
	Comment: Not Applicable			
K.	Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))			
	Submission states that the device: <input type="checkbox"/> is <input checked="" type="checkbox"/> is not an in vitro diagnostic device (IVD)			
	Comment: Not Applicable			
40.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:		X	
	a. Precision/reproducibility			
	b. Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff).			
	c. Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).			
	d. Analytical specificity			
	Comment: Not Applicable			
41.	a. If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable			

	Y	N/A	N
to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			
b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			
c. If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			

NAMIC RCS
Content and Organization of Information in a 510(k) for a Piston Syringe
“Guidance on the Content of Premarket Notification 510(k) Submissions for Piston Syringes” – April 1993

Guidance Document Requirement/Section	Support Documentation Location
II. Content and Organization of Information in a 510(k) a. Cover Letter	Section 3 of this submission.
II. Content and Organization of Information in a 510(k) b. Labels and Labeling	Attachment 1 of this submission.
II. Content and Organization of Information in a 510(k) c. Standards	Sections 2 and 18 of this submission.
II. Content and Organization of Information in a 510(k) d. Device Description	Section 10 of this submission.
II. Content and Organization of Information in a 510(k) e. Descriptive Comparison to a Legally Marketed Device	Section 11 of this submission.
II. Content and Organization of Information in a 510(k) f. Performance Data to Support Substantial Equivalence	Sections 12 and 15 of this submission.
II. Content and Organization of Information in a 510(k) g. Sterilization Information	Section 14 of this submission.
II. Content and Organization of Information in a 510(k) h. SMDA Information	Section 5 of this submission.
II. Content and Organization of Information in a 510(k) i. Sample	N/A
II. Content and Organization of Information in a 510(k) j. Anti-needlestick Requirements	N/A
III. Premarket Notification for Kits	Sections 10 and 19 of this submission.

Navilyst Medical, Inc.
NAMIC RCS, Abbreviated 510(k)
January 24, 2014

SECTION 1

MEDICAL DEVICE USER FEE COVER SHEET (FORM FDA 3601)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.	
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) NAVILYST MEDICAL INC 26 Forest St Marlborough MA 0175 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****4286		2. CONTACT NAME Lori Fitton 2.1 E-MAIL ADDRESS lfitton@angiodynamics.com 2.2 TELEPHONE NUMBER (include Area code) 508-6587938 2.3 FACSIMILE (FAX) NUMBER (Include Area code)	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm) <u>Select an application type:</u> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice <u>3.1 Select a center</u> <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER <u>3.2 Select one of the types below</u> <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)			
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:			
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially			
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA)). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below. Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]			
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b) (4)			22-Oct-2013

Online Payment

Step 3: Confirm Payment

Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: FDA User Fees

Pay.gov Tracking ID: (b) (4)

Agency Tracking ID: (b) (4)

Transaction Date and Time: (b) (4)

Payment Summary

Address Information

Account NAVILYST
Holder Name: MEDICAL INC

Billing Address: 26 Forest St

Billing Address 2:
City: Marlborough

State / Province: MA

Zip / Postal Code: 01752

Country: USA

Account Information

(b) (4)

Payment Information

Navilyst Medical, Inc.
NAMIC RCS, Abbreviated 510(k)
January 24, 2014

SECTION 2

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 24-January-2014	User Fee Payment ID Number (b) (4)	FDA Submission Document Number (if known) Unknown
---------------------------------------	--	--

SECTION A TYPE OF SUBMISSION

PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input checked="" type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Request for Feedback <input type="checkbox"/> Pre-Submission <input type="checkbox"/> Informational Meeting <input type="checkbox"/> Submission Issue Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Study Risk Determination <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Navilyst Medical, Inc.	Establishment Registration Number (if known) 3006716497		
Division Name (if applicable) Not Applicable	Phone Number (including area code) 508-658-7984		
Street Address 26 Forest Street	FAX Number (including area code) 508-658-7976		
City Marlborough	State / Province MA	ZIP/Postal Code 01752	Country USA
Contact Name Brandon M. Brackett			
Contact Title Specialist, Global Regulatory Affairs		Contact E-mail Address brandon.brackett@navilyst.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name Same			
Division Name (if applicable) Same		Phone Number (including area code) Same	
Street Address Same		FAX Number (including area code) Same	
City Same	State / Province Same	ZIP Code Same	Country Same
Contact Name Same			
Contact Title Same		Contact E-mail Address Same	

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (<i>specify</i>):		

SECTION D2 REASON FOR APPLICATION - IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final		
<input type="checkbox"/> Other Reason (<i>specify</i>):		

SECTION D3 REASON FOR SUBMISSION - 510(k)

<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<div style="background-color: black; color: red; padding: 5px;">(b) (4)</div>		

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	FMF	2		3	
5		6		7	
				8	

510 (k) summary attached
 510 (k) statement

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K113198	NMI Control Syringe	Navilyst Medical, Inc.
2	K875196	Disposable Coronary Control Syringe 12CC	Merit Medical Systems, Inc.
3	K873955	NAMIC Angiographic Syringe	Navilyst Medical, Inc.
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name
Syringe, Piston

	Trade or Proprietary or Model Name for This Device	Model Number
1	NAMIC RCS Syringe	H965701274111 - H965701274271
2		
3		
4		
5		

FDA document numbers of all prior related submissions (regardless of outcome)

1		3		5	6
7	8	9	10	11	12

Data Included in Submission

Laboratory Testing
 Animal Trials
 Human Trials

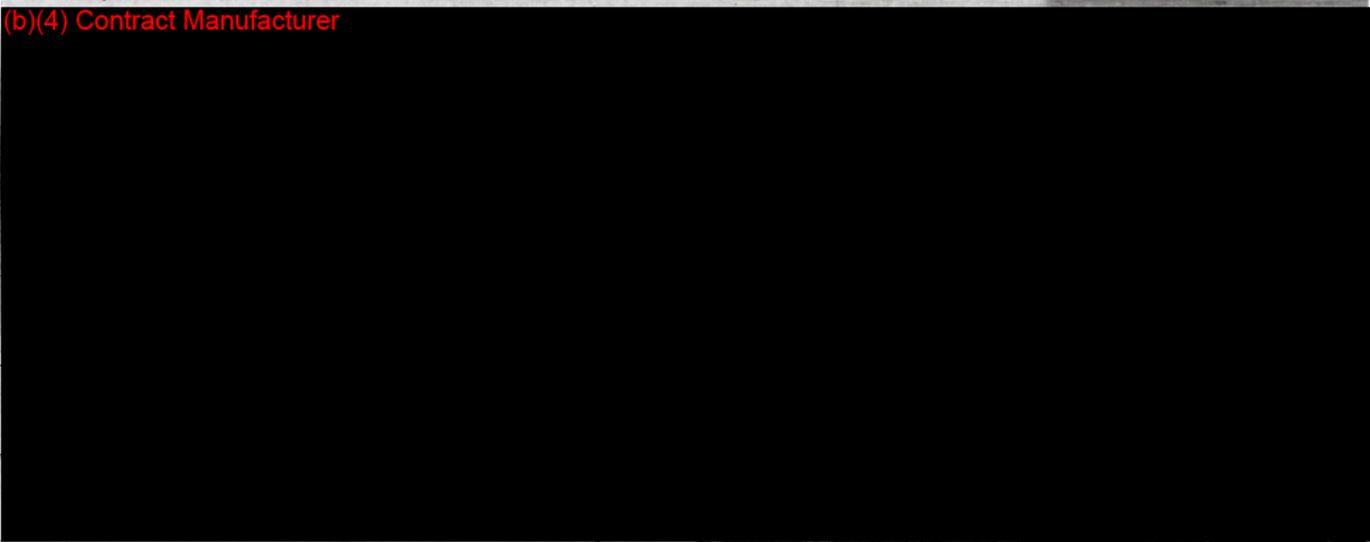
SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code FMF	C.F.R. Section (if applicable) 880.5860	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General Hospital		

Indications (from labeling)
The NAMIC RCS is intended to be used for the intra-arterial or intra-venous administration of radiographic contrast media and saline solutions during an angiographic procedure.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.		FDA Document Number (if known)	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number 1317056	
<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer		<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Navilyst Medical, Inc.		Establishment Registration Number 1317056	
Division Name (if applicable) Not Applicable		Phone Number (including area code) 508-658-7984	
Street Address 10 Glens Falls Technical Park		FAX Number (including area code) 508-658-7976	
City Glens Falls	State / Province NY	ZIP Code 12801	Country USA
Contact Name Brandon M. Brackett	Contact Title Specialist, Global Regulatory Affairs	Contact E-mail Address brandon.brackett@navilyst.com	

(b)(4) Contract Manufacturer



<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	
<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer		<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I

UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	10993-7	AAMI/ANSI/ISO	Biological Evaluation of Medical Devices, Part 7: Ethylene Oxide Sterilization Results	N/A	2008/(R)2012
2	11135-1	AAMI/ANSI/ISO	Sterilization of Health Care Products - Ethylene Oxide - Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices	N/A	01/01/2007
3	11138-1	AAMI/ANSI/ISO	Sterilization of Health Care Products - Biological Indicators - Part 1: General Requirements	N/A	2006/(R)2010
4	11737-1	AAMI/ANSI/ISO	Sterilization of Medical Devices - Microbiological Methods - Part 1: Determination of a Population of Microorganisms on Products	N/A	2006/(R)2011
5	ST72	AAMI/ANSI/ISO	Bacterial Endotoxins - Test Methods, Routine Monitoring, and Alternatives to Batch Testing	N/A	01/01/2011
6	11138-2	AAMI/ANSI/ISO	Sterilization of Health Care Products - Biological Indicators - Part 2: Biological Indicators for Ethylene Oxide Sterilization Processes	N/A	01/01/2009
7	556-1	EN	Sterilization of Medical Devices - Requirements for Medical Devices to be Designated "STERILE" - Part 1: Requirements for Terminally Sterilized Medical Devices	N/A	01/01/2001

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
 Food and Drug Administration
 Office of Chief Information Officer
 Paperwork Reduction Act (PRA) Staff
 1350 Piccard Drive, Room 400
 Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

	Standards Number	Standards Organization	Standards Title	Version	Date
8.	10993-1	AAMI/ANSI/ISO	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process	N/A	2009
9.	10993-5	AAMI/ANSI/ISO	Biological Evaluation of Medical Devices – Part 5: Tests for In-Vitro Cytotoxicity	N/A	2009
10.	10993-10	AAMI/ANSI/ISO	Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity	N/A	2010
11.	10993-11	AAMI/ANSI/ISO	Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity	N/A	2006/(R)2010
12.	10993-12	AAMI/ANSI/ISO	Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials	N/A	2012
13.	35-NF 30	USP	<151> - Pyrogen Test	N/A	2012
14.	35-NF 30	USP	<661> - Containers – Plastics: Physiochemical Tests	N/A	2012
15.	10993-4	EN ISO	Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood	N/A	2009
16.	594-2	ISO	Conical Fittings with 6% (Luer) Taper for Syringe, Needles, and Certain other Medical Equipment – Part 2: Lock Fittings	N/A	1998
17.	7886-1	ISO	Sterile Hypodermic Syringes for Single Use, Syringes for Manual Use	N/A	1997
18.	11607-1	AAMI/ANSI/ISO	Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems, and Packaging Systems, 3 rd Edition	N/A	2006
19.	11607-2	AAMI/ANSI/ISO	Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing, and Assembly Processes, 1 st Edition	N/A	2006
20.	F88/F88M	ASTM	Standard Test Method for Seal Strengths of Flexible Barrier Materials	N/A	2009
21.	F1980	ASTM	Standard Guide for Accelerated Aging of Sterile Medical Devices Packages	N/A	2007
22.	F1929-98	ASTM	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	N/A	2004
23.	F1886/F1886M	ASTM	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection	N/A	2009
24.	2A	ISTA	Performance Test for Packaged-Products 150 lb (68 kg) or Less	N/A	2011

Navilyst Medical, Inc.
NAMIC RCS, Abbreviated 510(k)
January 24, 2014

SECTION 3

510(K) COVER LETTER



26 Forest Street
Marlborough, MA 01752
508.658.7990 Tel

www.navilystmedical.com

January 24, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center - W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-002

Subject: Premarket Notification – Abbreviated 510(k) for proposed **NAMIC RCS**

Dear Sir/Madam:

According to Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 21 CFR §807 Subpart E, Navilyst Medical, Inc. (NMI) hereby submits one copy (one original paper copy and one exact duplicate copy in an electronic form) of this Abbreviated 510(k) Premarket Notification for the proposed **NAMIC RCS**. For ease of FDA review and based on prior FDA requests, we've provided an additional eCopy.

The purpose of this Abbreviated 510(k) is to achieve FDA clearance to introduce into commercial distribution an extension to our current syringe offerings, consisting of a range of sizes and colors. Design verification and validation activities have been completed, and data in regards to performance, shelf-life, biocompatibility, sterilization, and packaging have been provided to support the safety and effectiveness of the proposed device and to demonstrate substantial equivalence to the predicates.

The Abbreviated 510(k) approach was selected because an FDA guidance document exists ("*Guidance on the Content of Premarket Notification [510(K)] Submissions for Piston Syringes*") and there are FDA-recognized standards associated with this type of device, of which the device conforms with.

The predicate 510(k)'s to the proposed device include **K113198**, **K875196**, and **K873955** and there was no pre-submission correspondence (including Pre-Submission Requests) between Navilyst Medical, Inc. and the Agency related to this submission.

Navilyst Medical, Inc. considers the content of this letter and the existence of the 510(k) to be confidential commercial information and exempt from public disclosure; and therefore, requests that FDA does not disclose the existence or content of this 510(k) submission or this letter. Should you have any questions regarding this submission please contact me directly at 508-658-7984, or Ms. Wanda Carpinella, Director of Global Regulatory Affairs at 508-658-7929.

Sincerely,

A handwritten signature in black ink, appearing to read "BMB", is written over a horizontal line.

Brandon M. Brackett
Specialist, Global Regulatory Affairs
Navilyst Medical, Inc.
Phone: 508-658-7984
Fax: 508-658-7976
E-mail: brandon.brackett@navilyst.com

Note: the eCopy is an exact duplicate of the paper copy.

SECTION 4

INDICATIONS FOR USE STATEMENT

INDICATIONS FOR USE

510(k) Number (if Known): _____

Device Name: NAMIC RCS

Indications for Use:

The NAMIC RCS is intended to be used for the intra-arterial or intra-venous administration of radiographic contrast media and saline solutions during an angiographic procedure.

Prescription Use
(21 CFR 801 Subpart D)



And/Or

AND/OR Over-The-Counter Use:
(21 CFR 801 Subpart C)



(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

SECTION 5

510(K) SUMMARY

510(k) SUMMARY FOR THE NAMIC RCS

Date prepared: January 24, 2014

A. Sponsor

Navilyst Medical, Inc
26 Forest Street
Marlborough, MA 01752

B. Contact

Brandon M. Brackett
Specialist, Global Regulatory Affairs
508-658-7984

OR Wanda Carpinella
Director of Global Regulatory Affairs
508-658-7929

C. Device Name

Trade Name	NAMIC RCS
Common/Usual name:	Piston Syringe
Classification Name:	Syringe, Piston (21CFR§880.5860, Class II)
Classification Panel:	General Hospital

D. Predicate Device(s)

Common/Usual name:	Piston Syringe
Classification Name	Syringe, Piston - 21CFR§880.5860, Class II
Classification Panel:	General Hospital
Premarket Notification	K113198, K875196, K873955

E. Device Description

Intended Use

The NAMIC RCS is intended to be used for the intra-arterial or intra-venous administration of radiographic contrast media and saline solutions during an angiographic procedure.

F. Summary of Similarities and Differences in Technological Characteristics and Performance

The proposed NAMIC RCS syringes incorporate similar materials, design, components, technological characteristics, and intended us as the predicate syringes.

G. Performance Data

The NAMIC RCS is substantially equivalent to the predicate devices based on comparison of technological characteristics and the results of non-clinical tests which included the performance evaluation conducted in accordance with the following FDA guidance documents, international standards, and testing which included:

- FDA's "Guidance on the Content of Premarket Notification 510(k) Submissions for Piston Syringes dated April 1993"
- ISO 7886-1:1997 "Sterile Hypodermic Syringes for Single Use – Part 1: Syringes for Manual Use"
- ISO 594-2:1998 "Conical Fittings 6% (Luer) Taper for Syringes, Needles, Certain Other Medical Equipment – Part 2: Lock Fittings"

H. Conclusion

The results of the non-clinical testing and a comparison of similarities and differences demonstrate that the proposed and predicate devices are substantially equivalent.

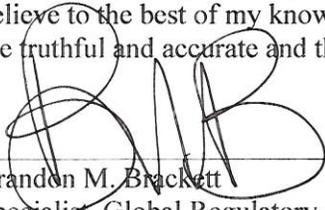
SECTION 6

TRUTHFUL AND ACCURACY CERTIFICATION STATEMENT

Navilyst Medical, Inc.
NAMIC RCS, Abbreviated 510(k)
January 24, 2014

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(AS REQUIRED BY 21 CFR 807.87(K))**

I certify that, in my capacity as a Specialist of Global Regulatory Affairs for Navilyst Medical, Inc., I believe to the best of my knowledge, that the data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



Brandon M. Brackett
Specialist, Global Regulatory Affairs
Navilyst Medical, Inc.

24. JANUARY. 2014
Date

Premarket Notification Number [510(k)] Number: _____

*Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter.)

SECTION 7

CLASS III CERTIFICATION AND SUMMARY STATEMENT

*The proposed device has been previously classified by the FDA as:

- Class II per 21CFR§880.5860, Pro-Code FMF

Therefore, **NO CLASS III CERTIFICATION AND SUMMARY STATEMENT** is required in support of this submission.

SECTION 8

FINANCIAL CERTIFICATION/DISCLOSURE STATEMENT

*There were **NO** clinical trials conducted in support of this submission.

Therefore, **NO FINANCIAL CERTIFICATION/DISCLOSURE STATEMENT** is required.

SECTION 9

EXECUTIVE SUMMARY

Navilyst Medical, Inc. has submitted this Abbreviated 510(k) in order to achieve FDA clearance to introduce into US commercial distribution the proposed NAMIC Radiology Control Syringe (RCS) devices. (b) (4)

Control syringes are commonly used devices in fluid management procedures, and are typically marketed in a variety of sizes and/or colors, having distal barrel tips with/without a reservoir, syringe barrels having fixed male Luer lock or rotating male Luer adaptor tips, and with finger grips.

(b) (4)

Similar to the predicate devices, the proposed NAMIC RCS syringes are manual, piston-type syringes sharing the same fundamental scientific technology as one another. Furthermore, the proposed syringes are:

- available in a variety of sizes including (b) (4)
- available in multiple colors including (b)(4)Trade Secret Process-Product specs ;
- (b) (4)

Also, the proposed and predicate devices share an equivalent intended use and indications for use statement:

“The NAMIC RCS is intended to be used for the intra-arterial or intra-venous administration of radiographic contrast media and saline solutions during an angiographic procedure.”

(b) (4)

Section 10 of this submission provides a more detailed description of the proposed device, and **Section 11** includes a discussion of the similarities and differences between the proposed and predicate syringes.

(b) (4)

conducted in accordance with the following international standards and FDA Guidance Documents:

- FDA’s “Guidance on the Content of Premarket Notification 510(k) Submissions for Piston Syringes dated April 1993”
- ISO 7886-1:1997 “Sterile Hypodermic Syringes for Single Use – Part 1: Syringes for Manual Use”
- ISO 594-2:1998 “Conical Fittings 6% (Luer) Taper for Syringes, Needles, Certain Other Medical Equipment – Part 2: Lock Fittings”

SECTION 10

DEVICE DESCRIPTION

The proposed NAMIC RCS devices are manual, piston-type syringes used to administer fluids, such as saline and contrast media, used during (b) (4). Similar to the predicate devices, they consist of:

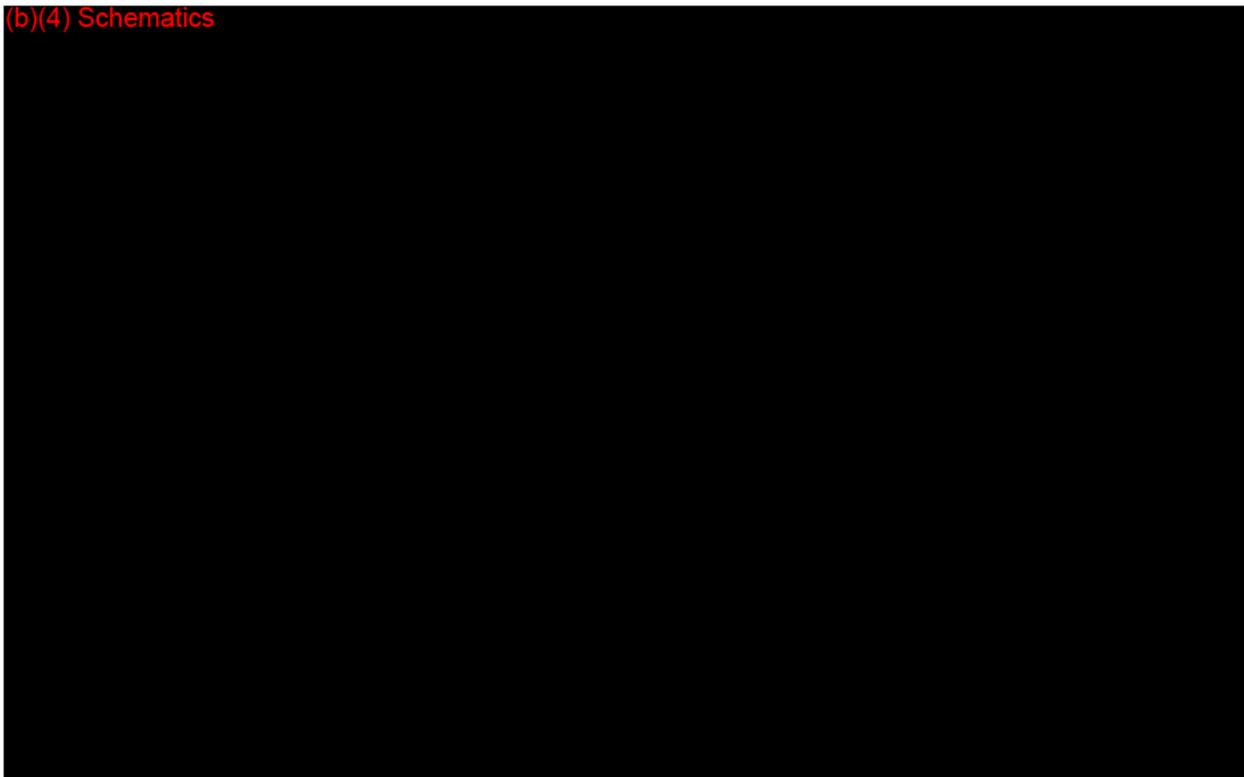
- a (b) (4) barrel with (b) (4) markings along the barrel (b) (4)
- a piston (commonly called a plunger) which allows for aspiration of fluid into the syringe for injection;
- a variety of piston colors (b) (4) and
- a stopper (b) (4)

Like the predicate devices, the syringe tip Luer has a fixed male Luer lock (b) (4). All configurations of the proposed devices are provided with a (b) (4) with a (b) (4) to allow for single handed infusion of fluids.

Furthermore, (b) (4) will be (b) (4). The proposed syringes will be (b) (4).

Figure 1 below shows (b) (4). Figures 2 thru 6 include the (b) (4). Figures 7 and 8 (b) (4).

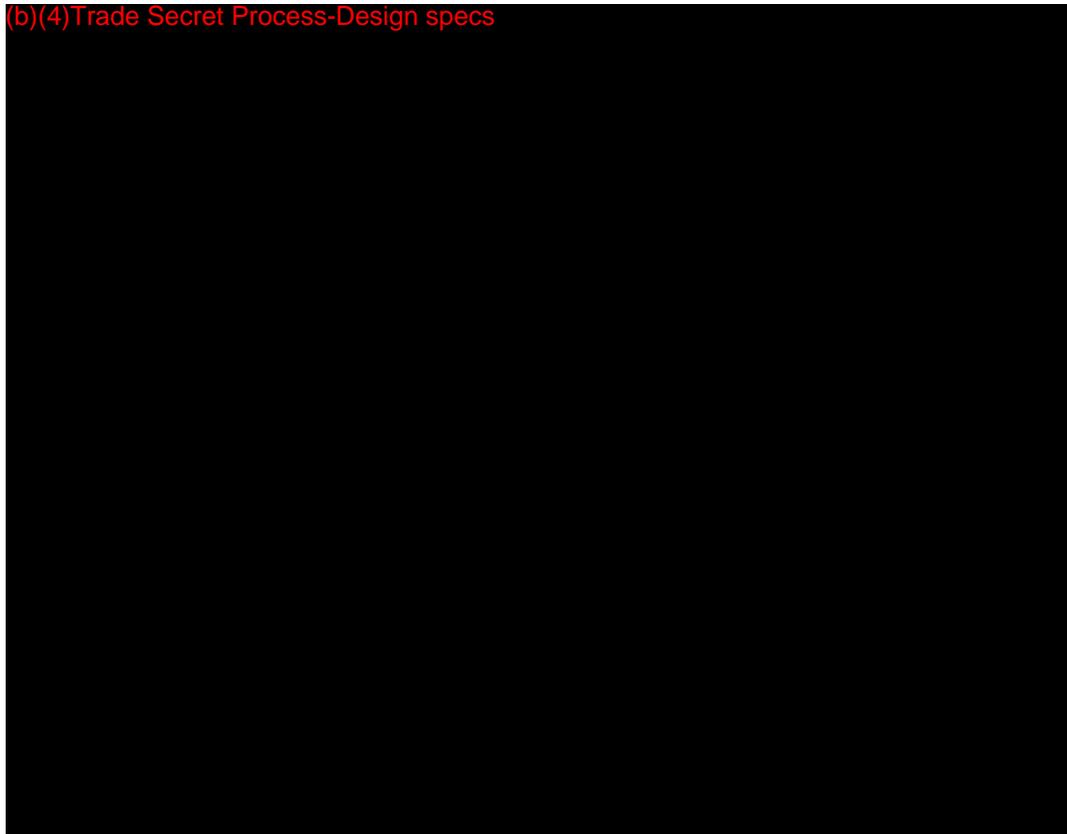
(b)(4) Schematics



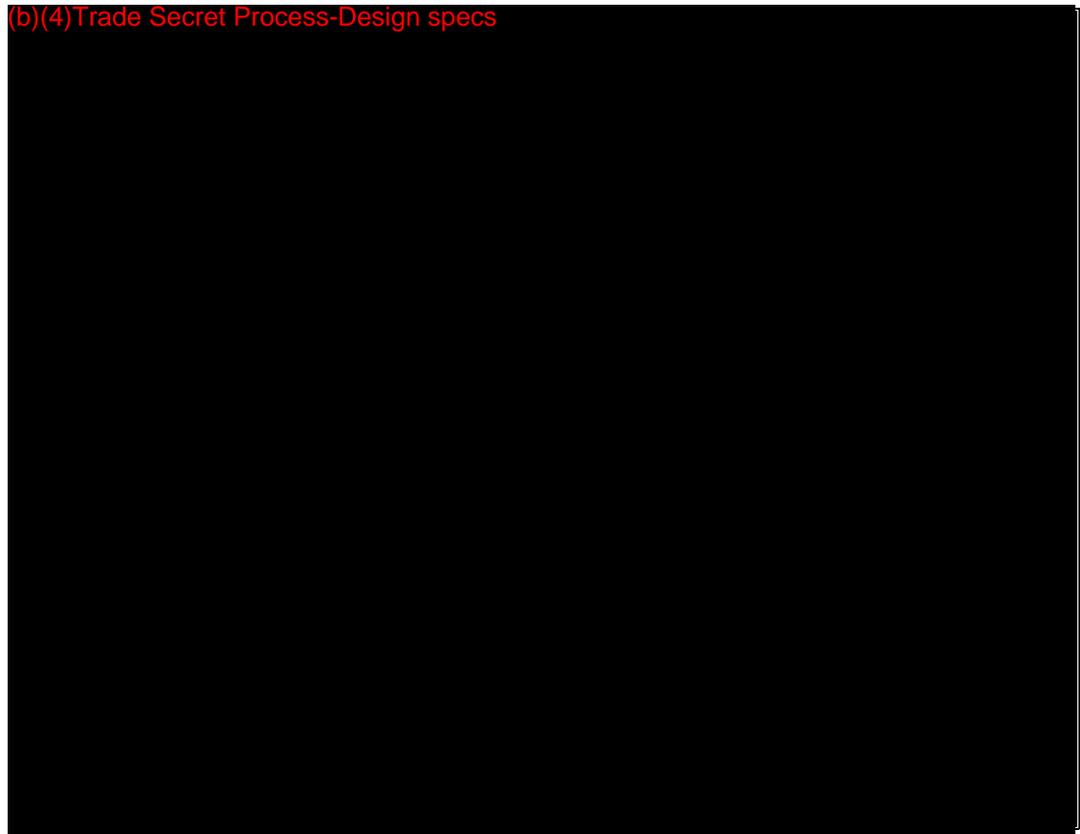
Principle of Operation

A control syringe is intended to be used by a healthcare professional in a variety of angiographic procedures in which it is necessary to inject or aspirate (to fill the syringe) fluids such as contrast media or saline. During infusion the piston is depressed, travelling the axial length of the syringe barrel. The applied manual pressure allows fluids to exit through the distal end of the syringe tip.

Drawings and Photograph Figures



(b)(4) Trade Secret Process-Design specs



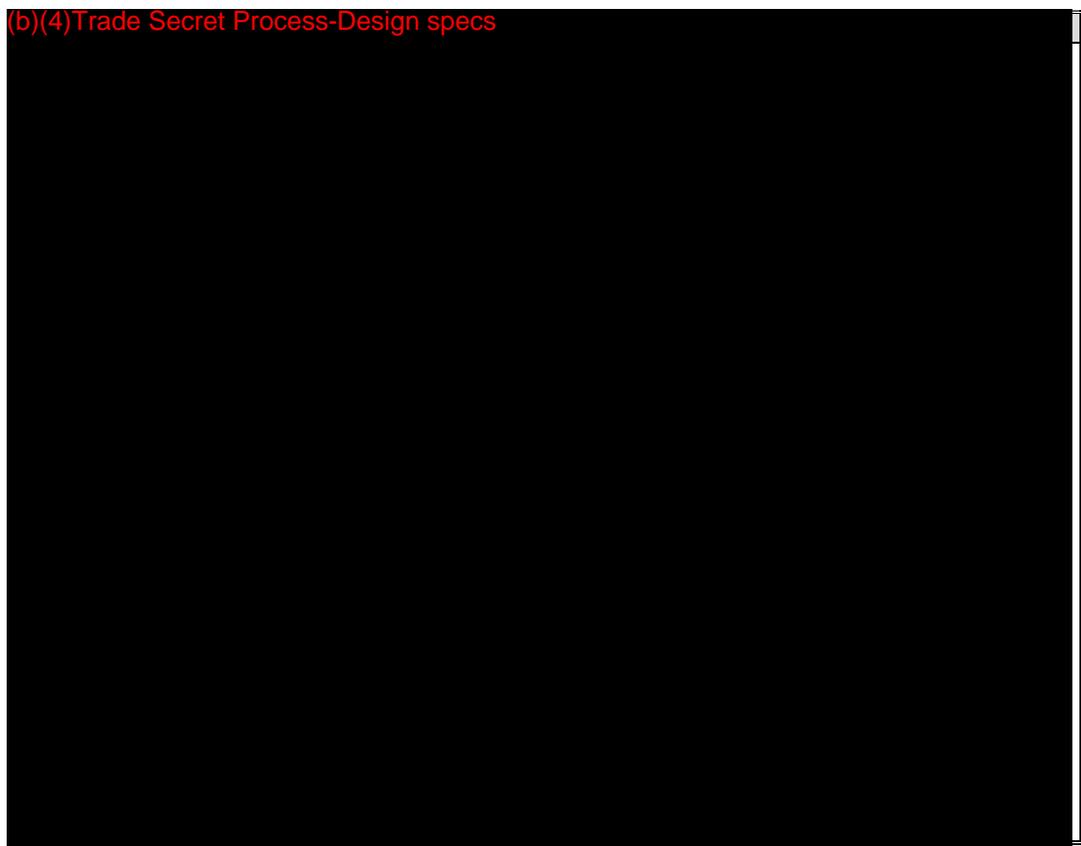
(b)(4) Trade Secret Process-Design specs



(b)(4)Trade Secret Process-Design specs



(b)(4)Trade Secret Process-Design specs



Figures 7 and 8 include pictures of the proposed NAMIC RCS devices (White Plunger is represented)

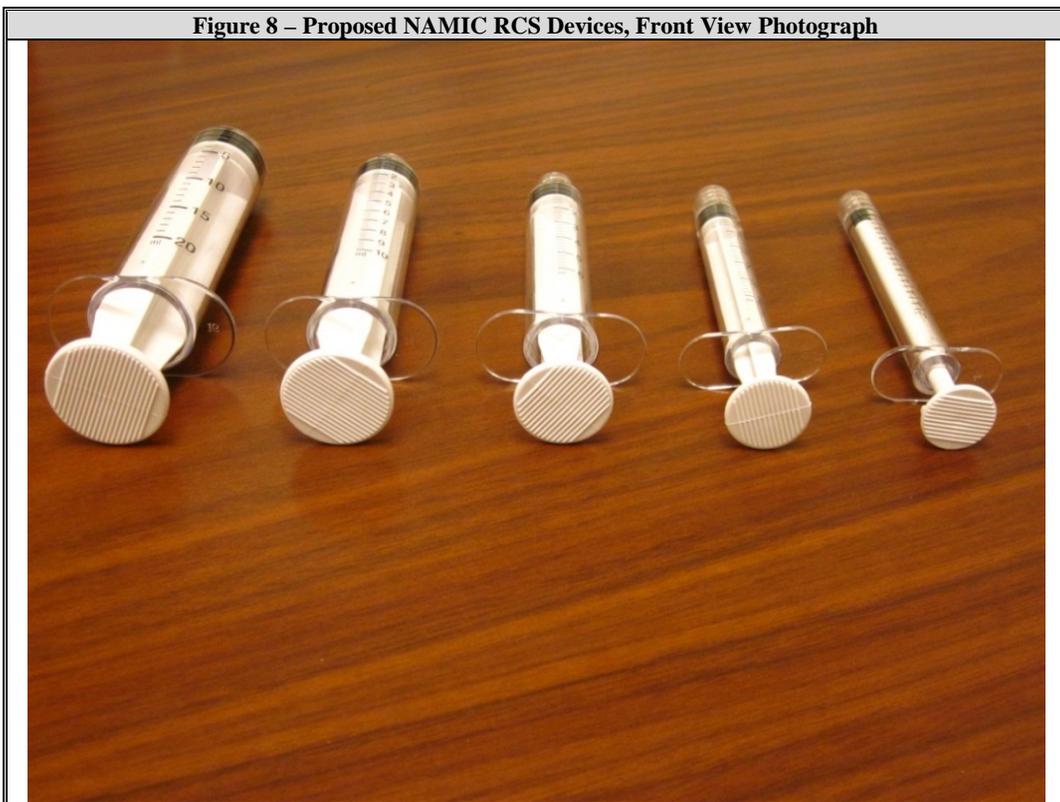
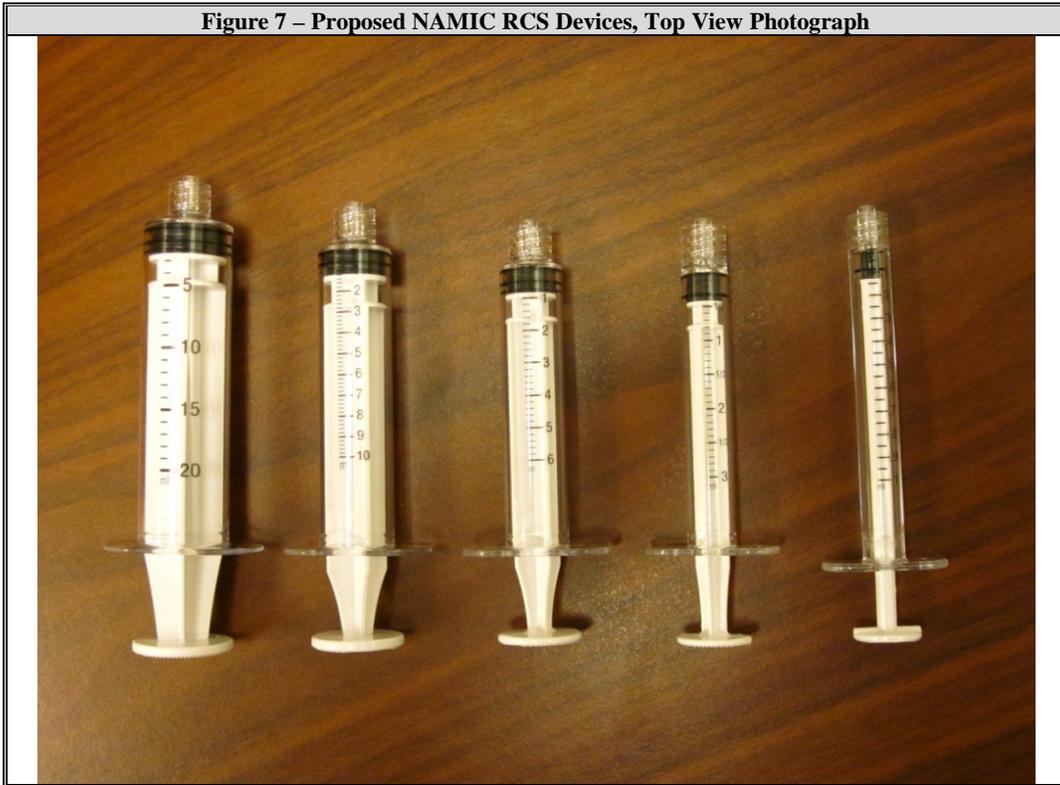


Table #1 below lists the components of the proposed NAMIC RCS devices (b)(4)Trade Secret
Process-Product specs

(b)(4)Trade Secret Process-Product specs



SECTION 11

SUBSTANTIAL EQUIVALENCE DISCUSSION

SUMMARY OF SIMILARITIES AND DIFFERENCES

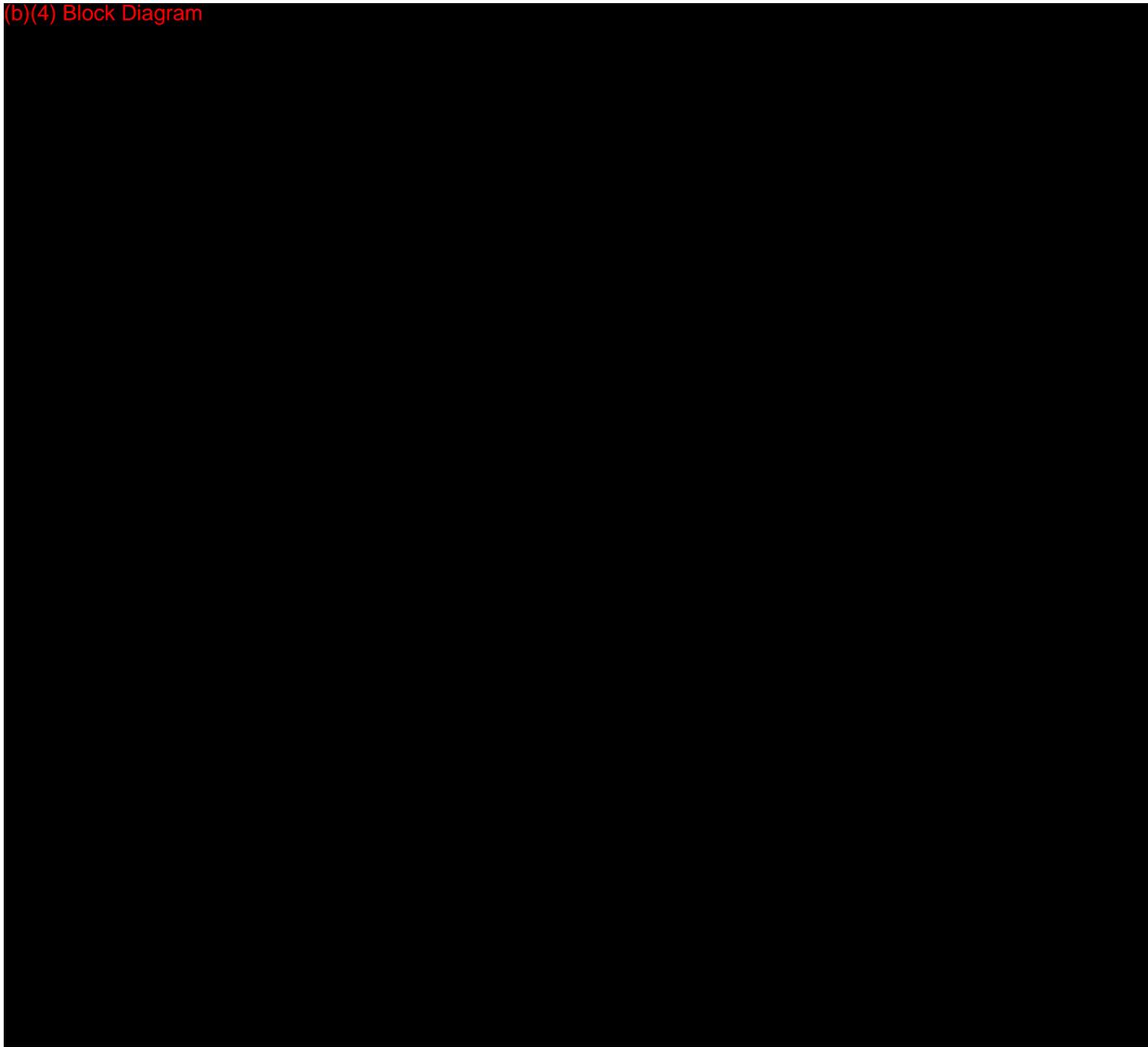
The proposed NAMIC RCS syringes are substantially equivalent to the predicate NMI syringes cleared via **K873955** and **K113198**, as well as the Merit syringes cleared via **K875196** in terms of intended use, materials, design, principle of operation, sterility, and packaging. **Table #3** compares similarities and differences of the proposed NAMIC RCS syringes to the predicate syringes.

The proposed devices are substantially equivalent in regards to sizes, materials, principles of operation, and intended use to the syringes cleared via **K875196**, **K113198**, **K024052** and **K070856**. To demonstrate performance equivalence, in support of a substantial equivalence determination, the proposed devices were compared to syringes cleared via **K875196** (Merit), **K873955**, and **K113198** (Navilyst Medical). All of the referenced devices were cleared by FDA with ProCode FMF, under 21 CFR 880.5860.

SUMMARY OF SIMILARITIES AND DIFFERENCES

The 510(k) “Substantial Equivalence” Decision-Making Process, as outlined in ODE Guidance Document #K86-3, *Guidance on the CDRH Premarket Notification Review Program*, was used along with the devices testing, to confirm substantial equivalence of the proposed device to the predicate device as described. The 510(k) Decision Making-Flowchart shown below was also utilized to show substantial equivalence. The decision path used to arrive at the substantial equivalence determination is highlighted. **Table #2** contains answers to Decision Tree questions.

(b)(4) Block Diagram



(b)(4)Trade Secret Process-Product specs



Conclusion

Based upon a comparison of similarities and differences of the proposed and predicate devices, the

(b)
(4)Trade
de

(b)(4)Trade Secret Process-Product specs



SECTION 12

PERFORMANCE TESTING

SUMMARY OF PERFORMANCE EVALUATION

In support of substantial equivalency, we've conducted and summarized testing for the proposed NAMIC RCS, (b)(4)Trade Secret Process-Product specs

(b)(4)Trade Secret Process-Product specs

PACKAGING TESTING

(b)(4)Trade Secret Process-Product specs

SHELF LIFE

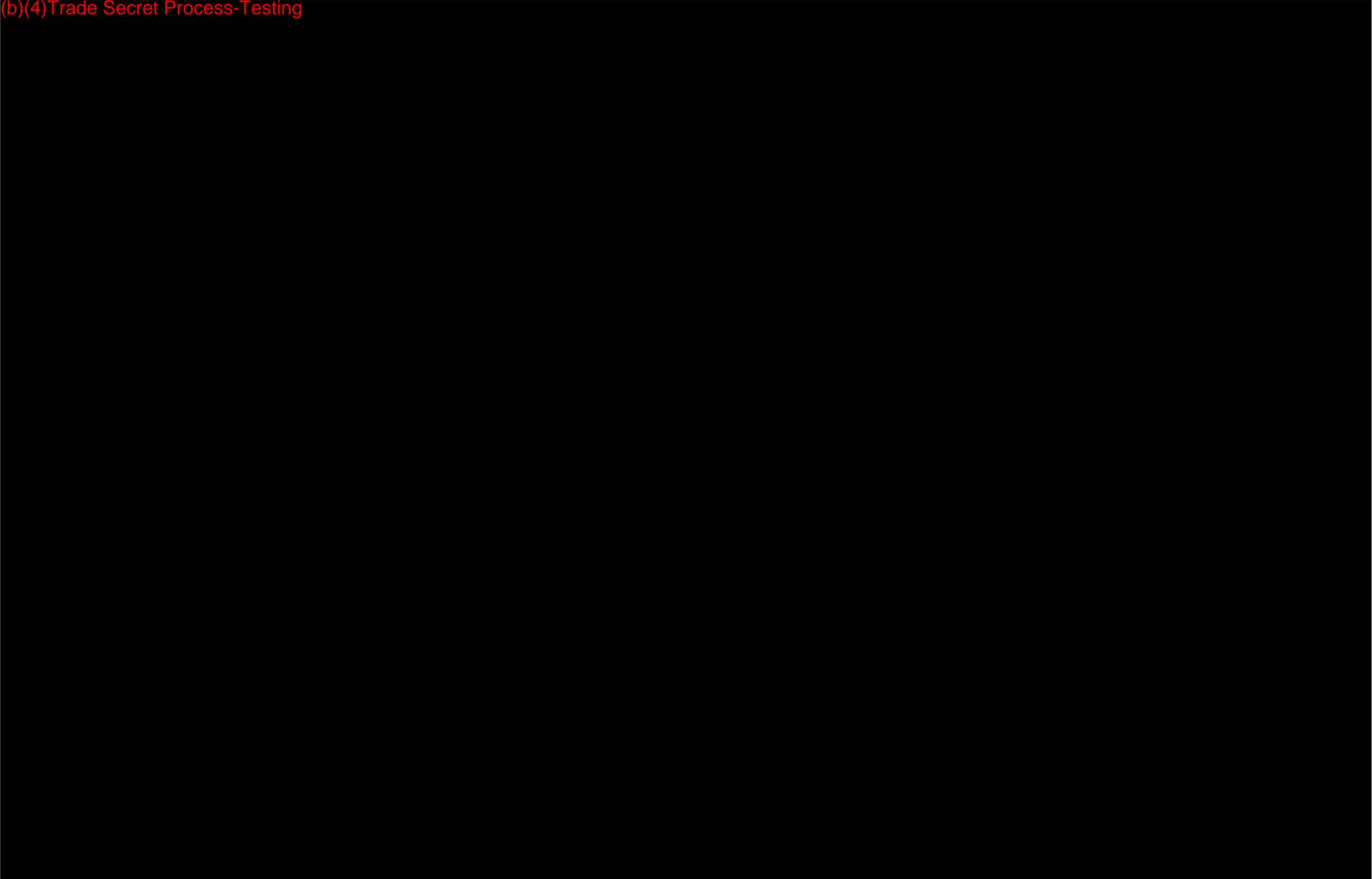
(b)(4)

Therefore, the labeled expiry date for the proposed NAMIC RCS syringes is supported for 1 year.

CONCLUSION

In summary, the proposed NAMIC RCS syringes met all the established acceptance criteria and performance specifications. (b)(4)Trade Secret Process-Product specs

(b)(4) Trade Secret Process-Testing



(b)(4) Trade Secret Process-Testing



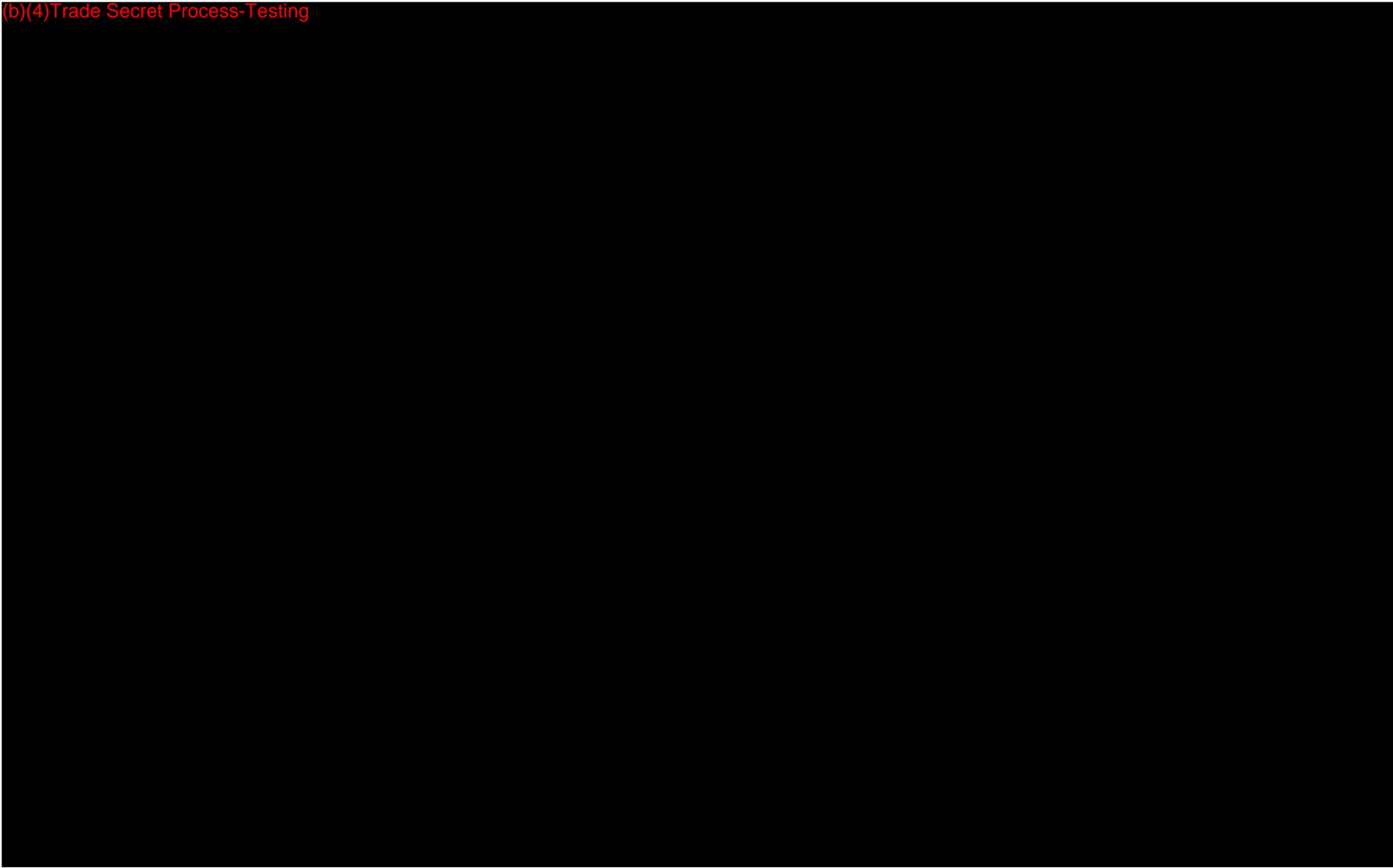
Navilyst Medical, Inc.
NAMIC RCS, Abbreviated 510(k)
January 24, 2014

(b)(4) Trade Secret Process-Testing

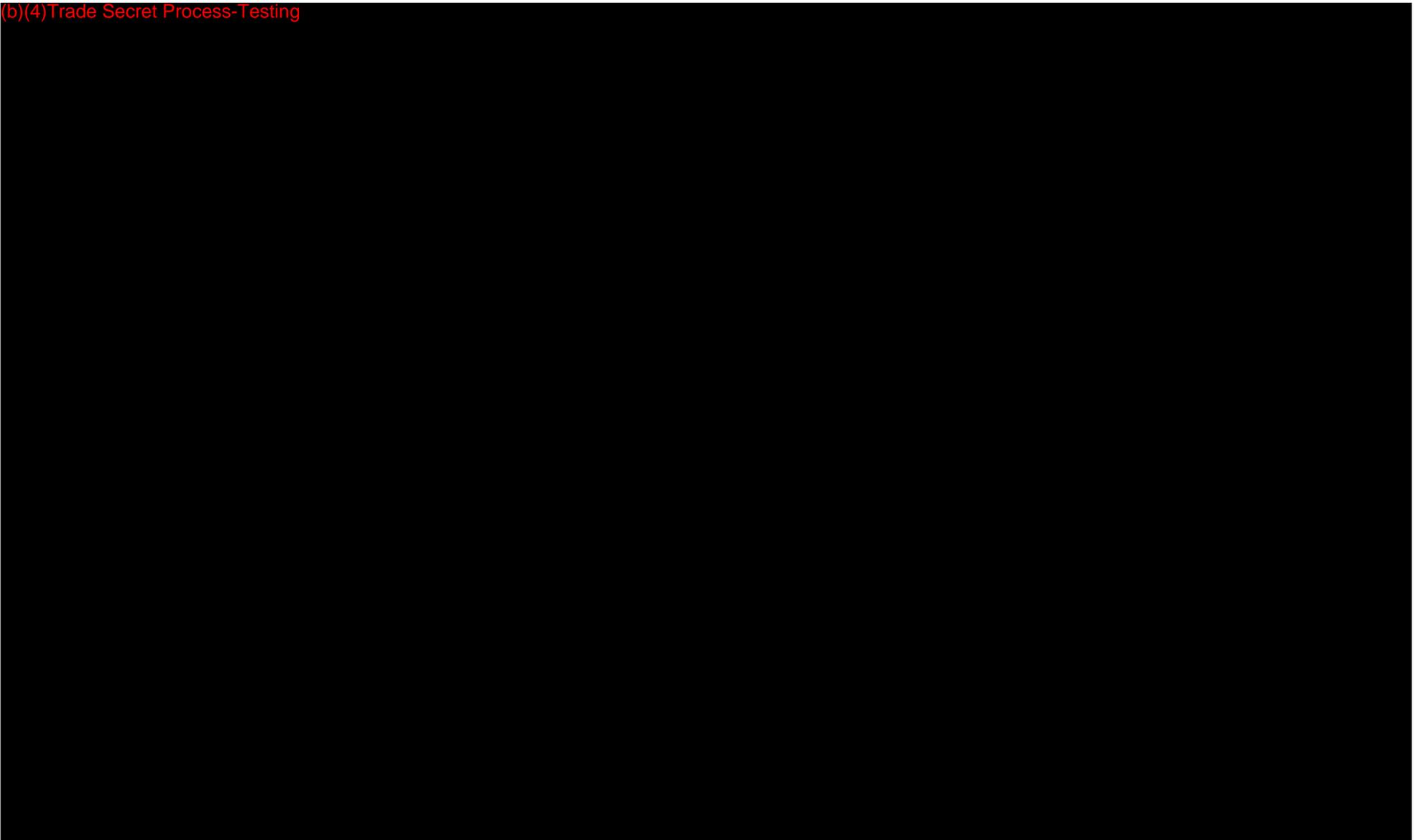


Confidential and Proprietary to Navilyst Medical, Inc.

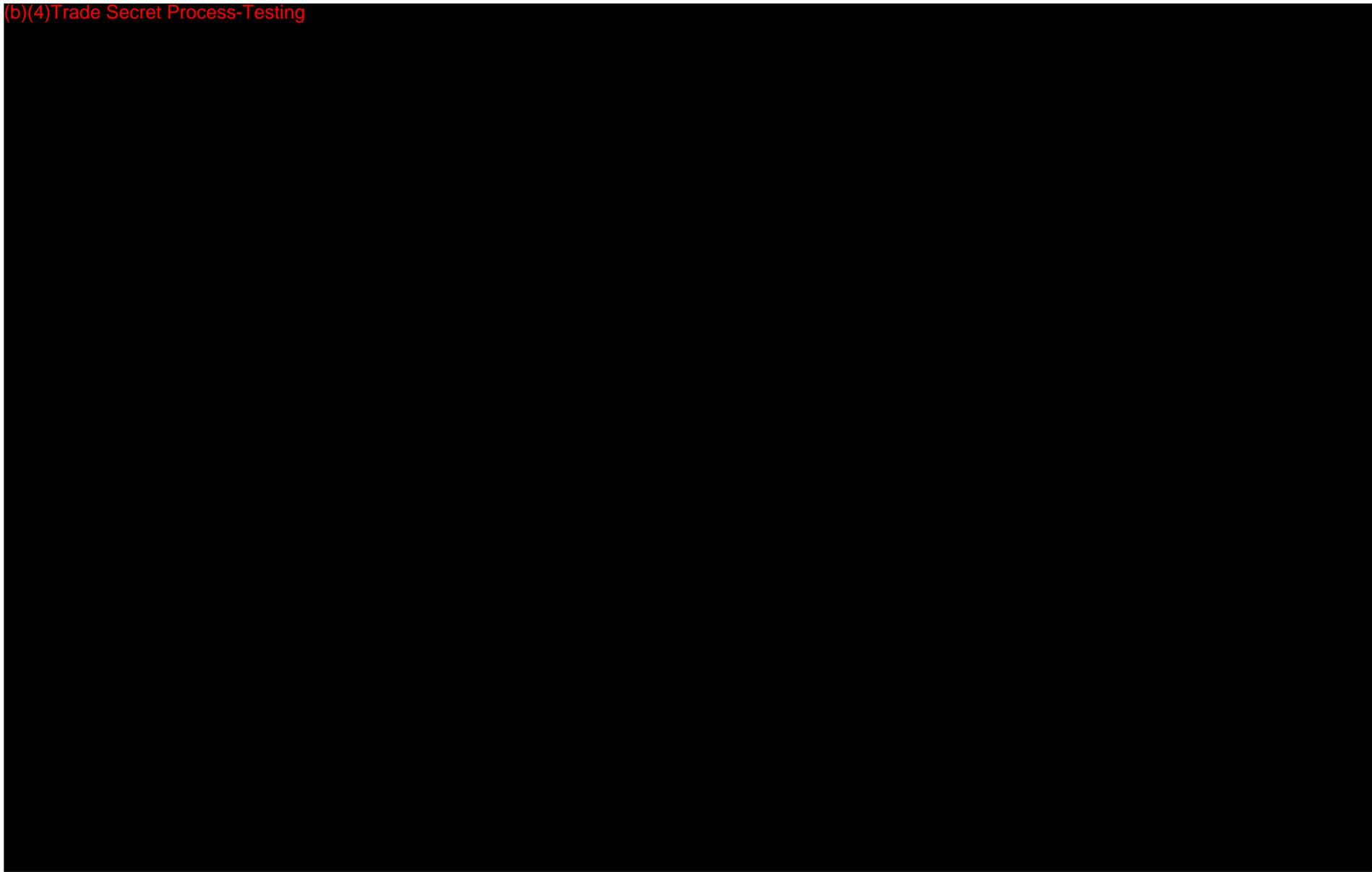
(b)(4)Trade Secret Process-Testing



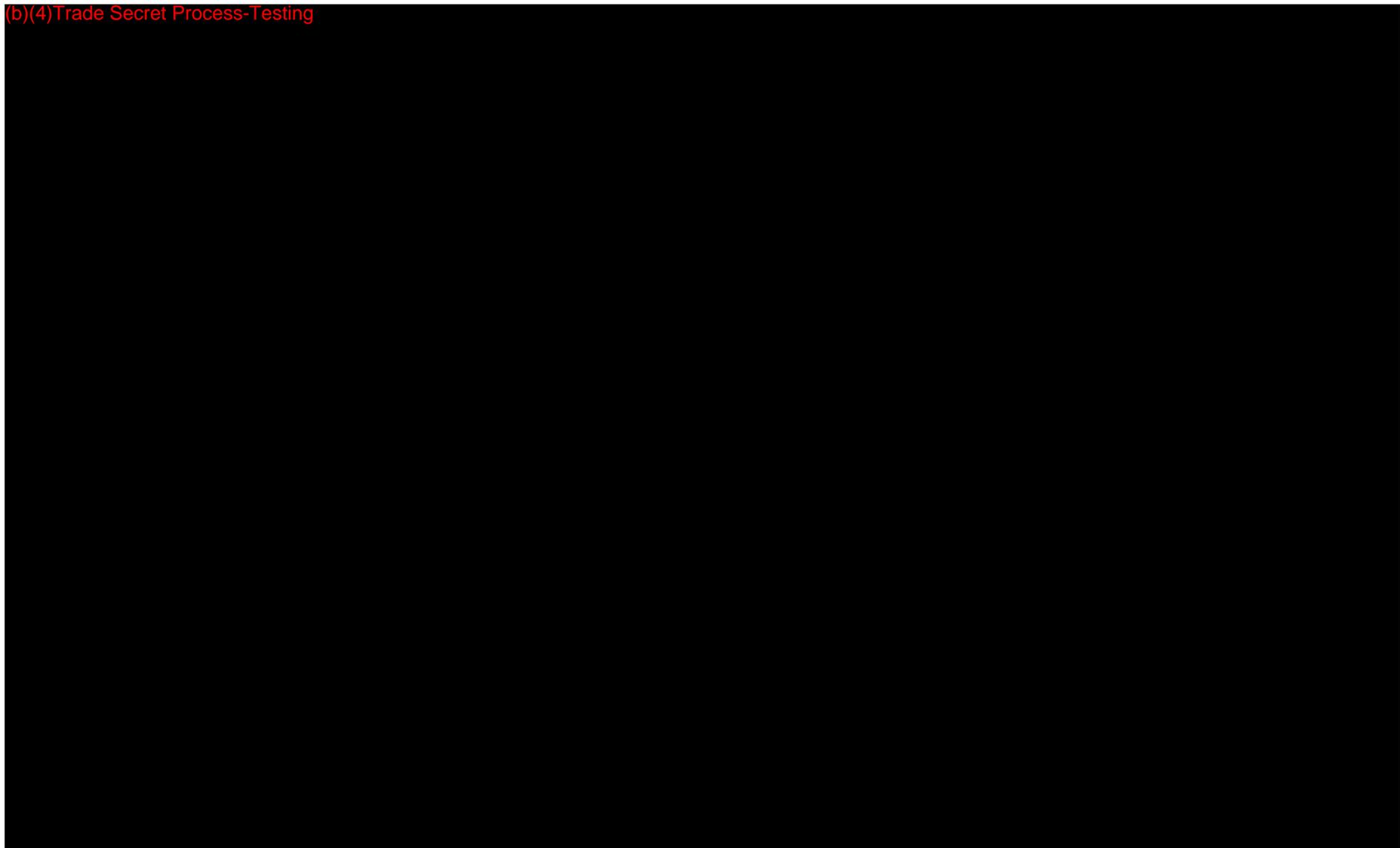
(b)(4) Trade Secret Process-Testing



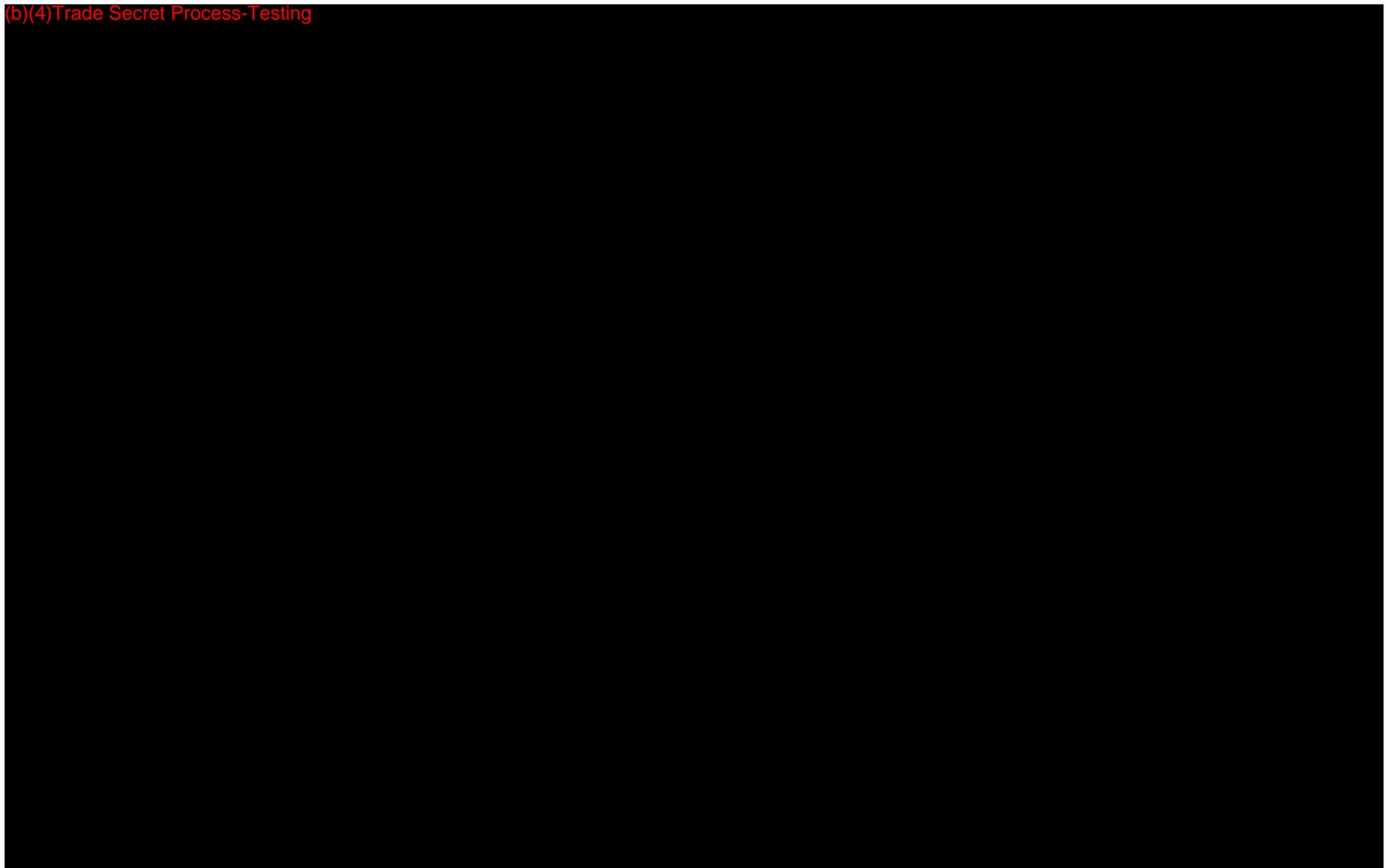
(b)(4) Trade Secret Process-Testing



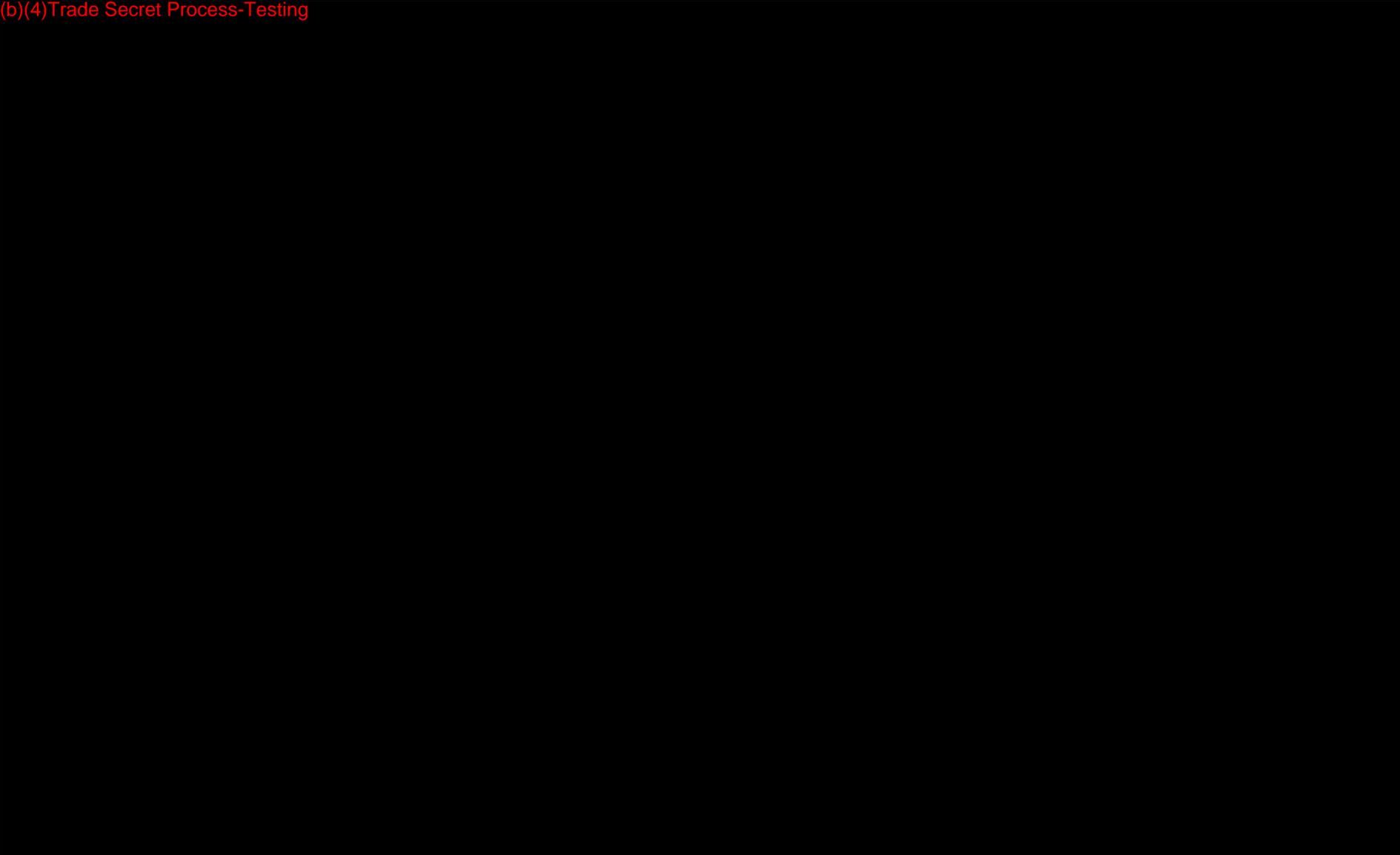
(b)(4)Trade Secret Process-Testing



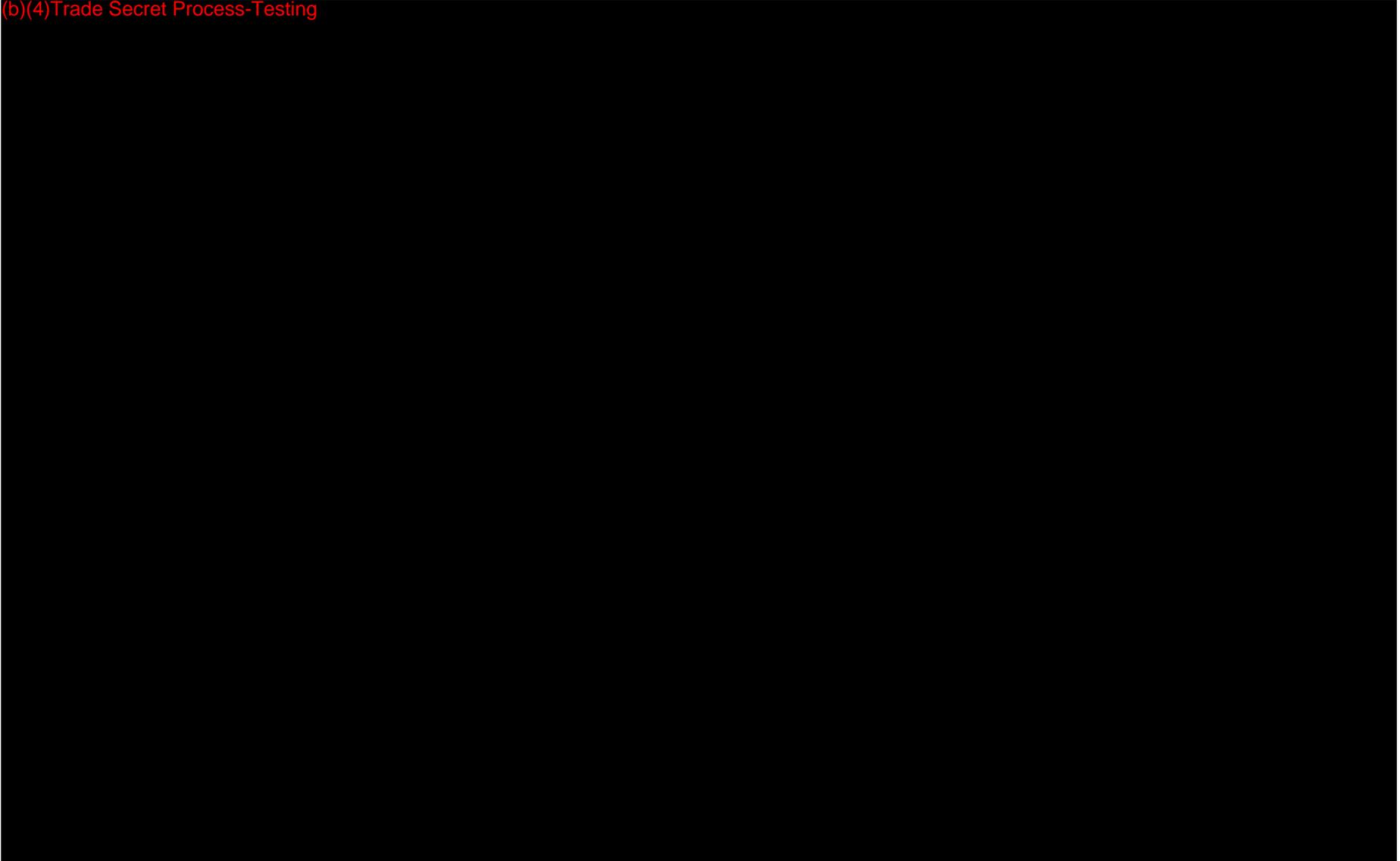
(b)(4) Trade Secret Process-Testing



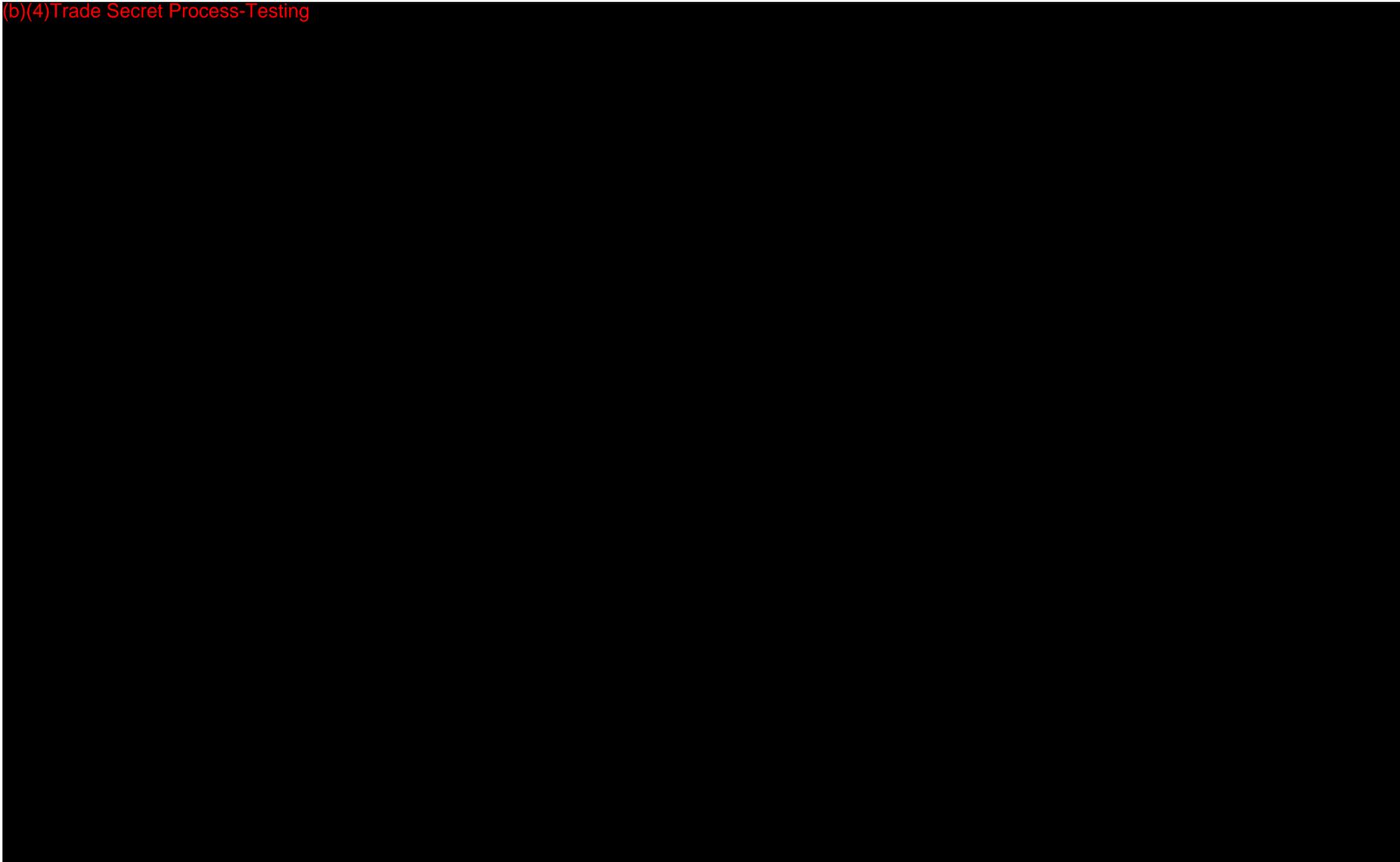
(b)(4) Trade Secret Process-Testing



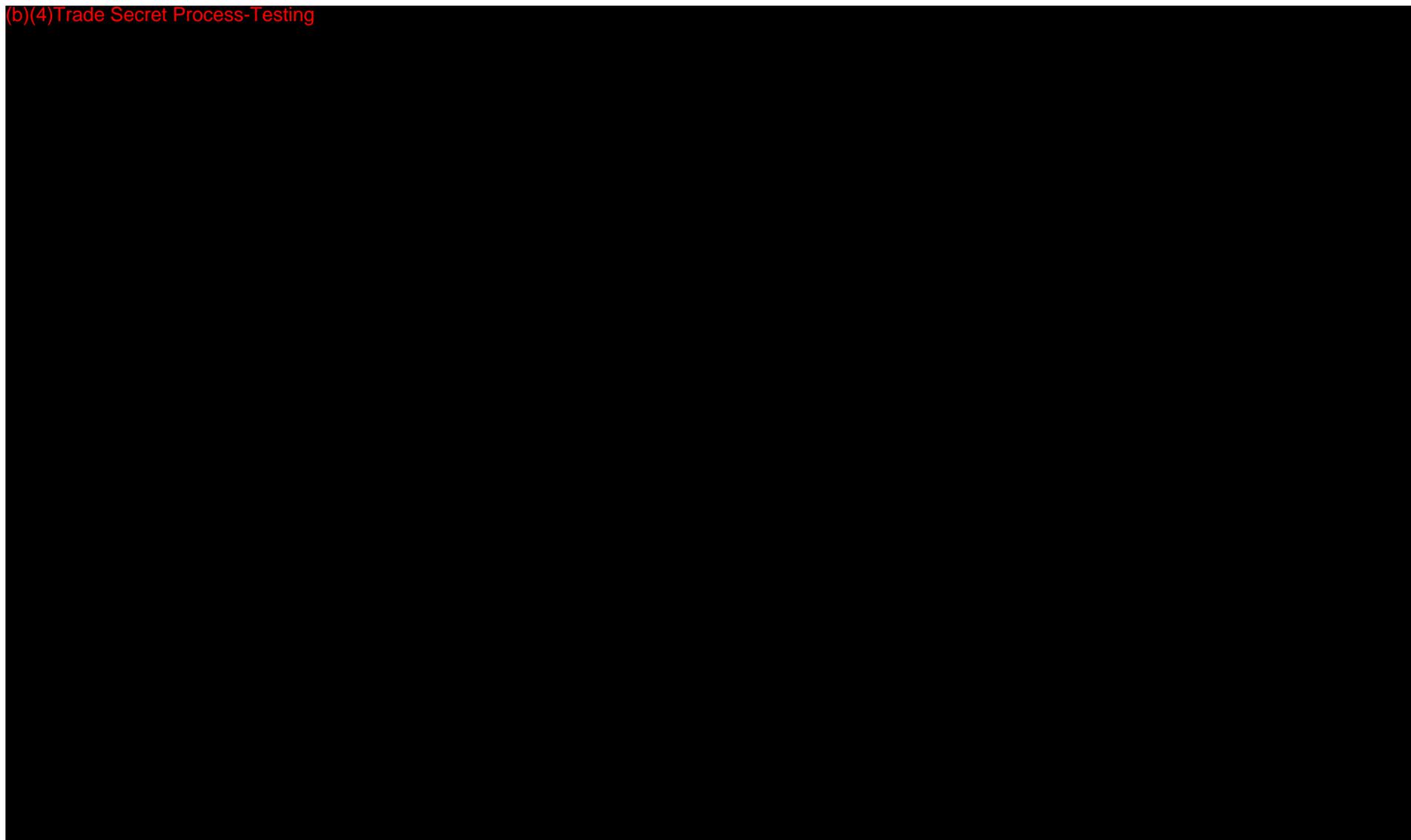
(b)(4)Trade Secret Process-Testing



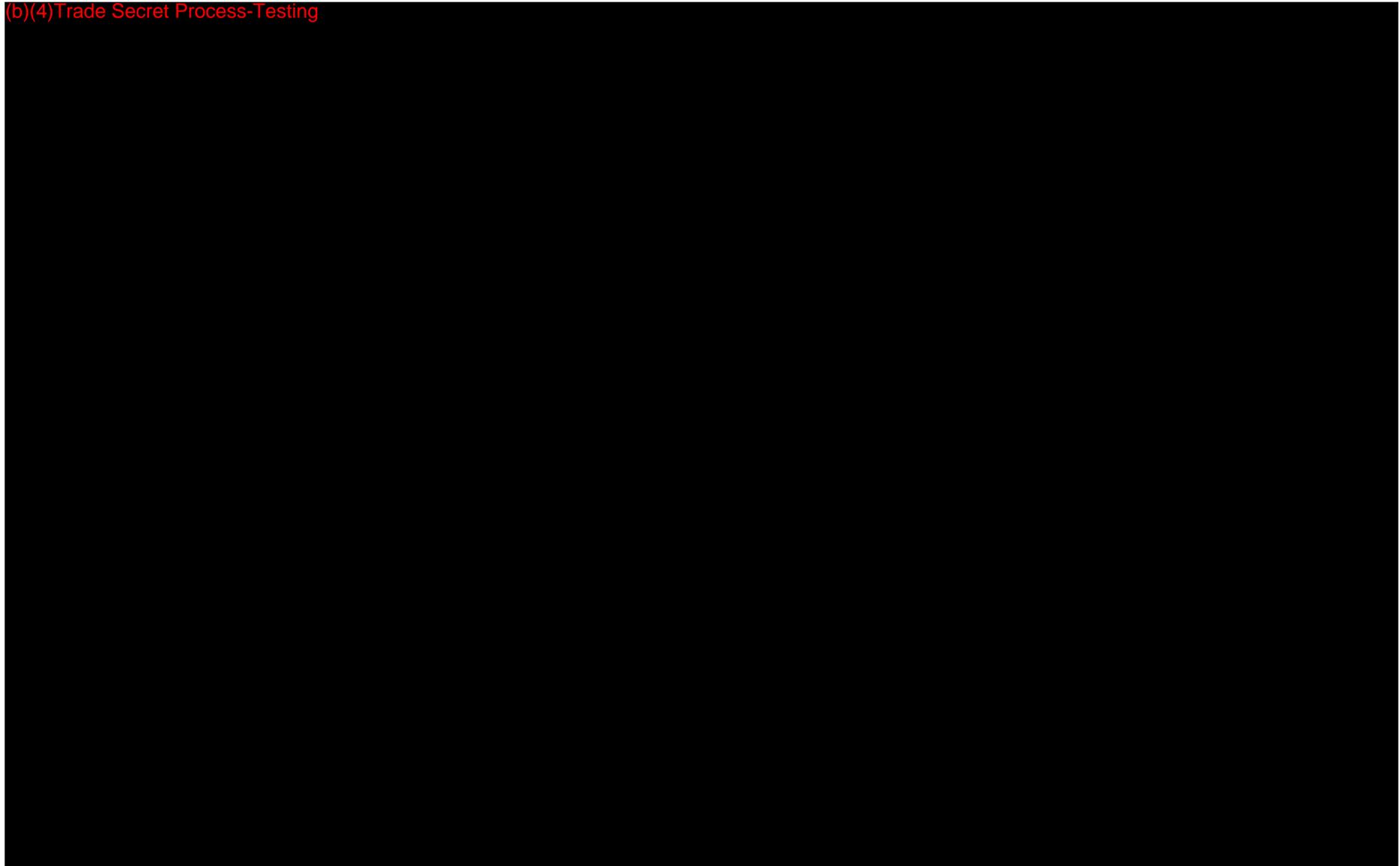
(b)(4)Trade Secret Process-Testing



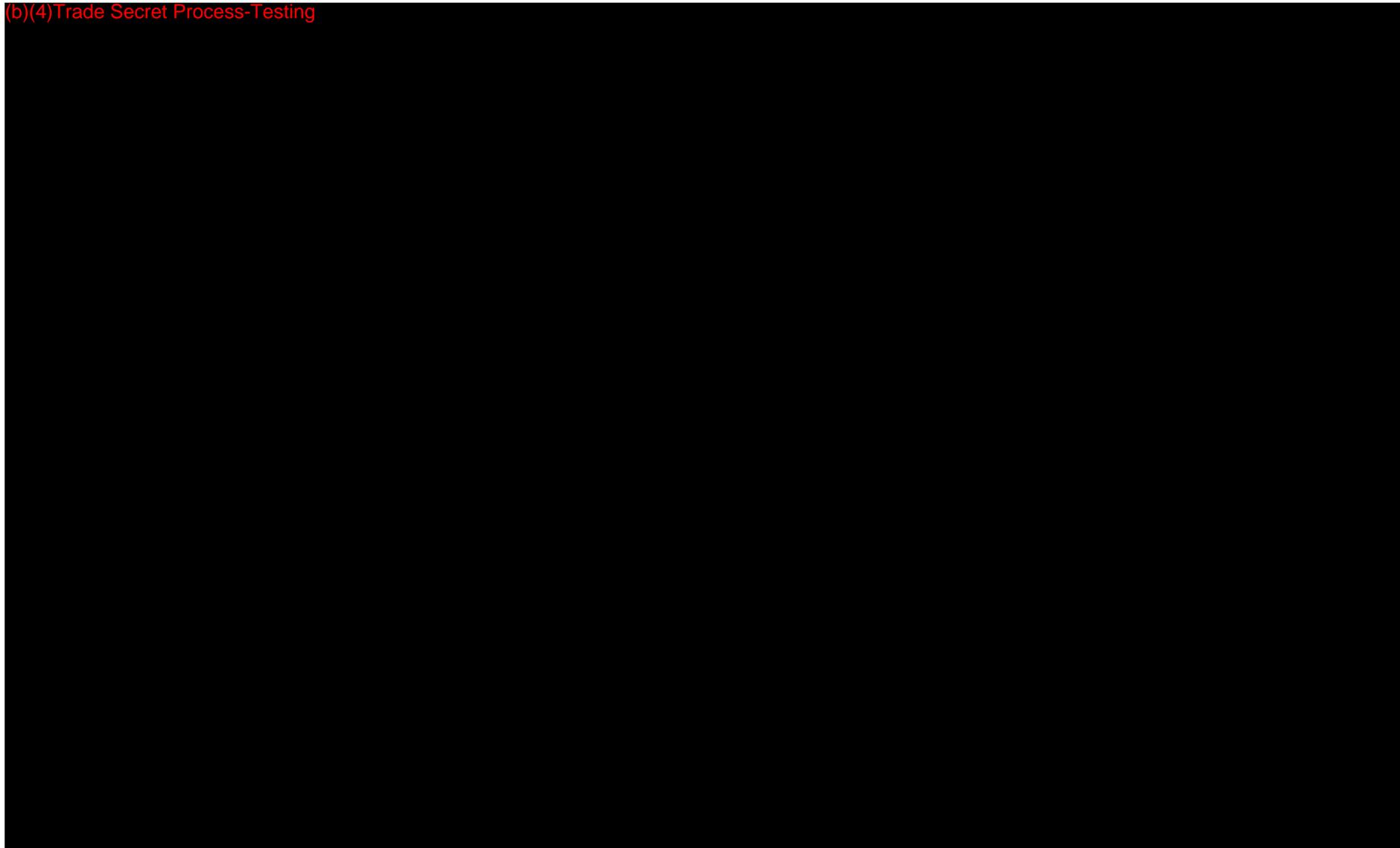
(b)(4)Trade Secret Process-Testing



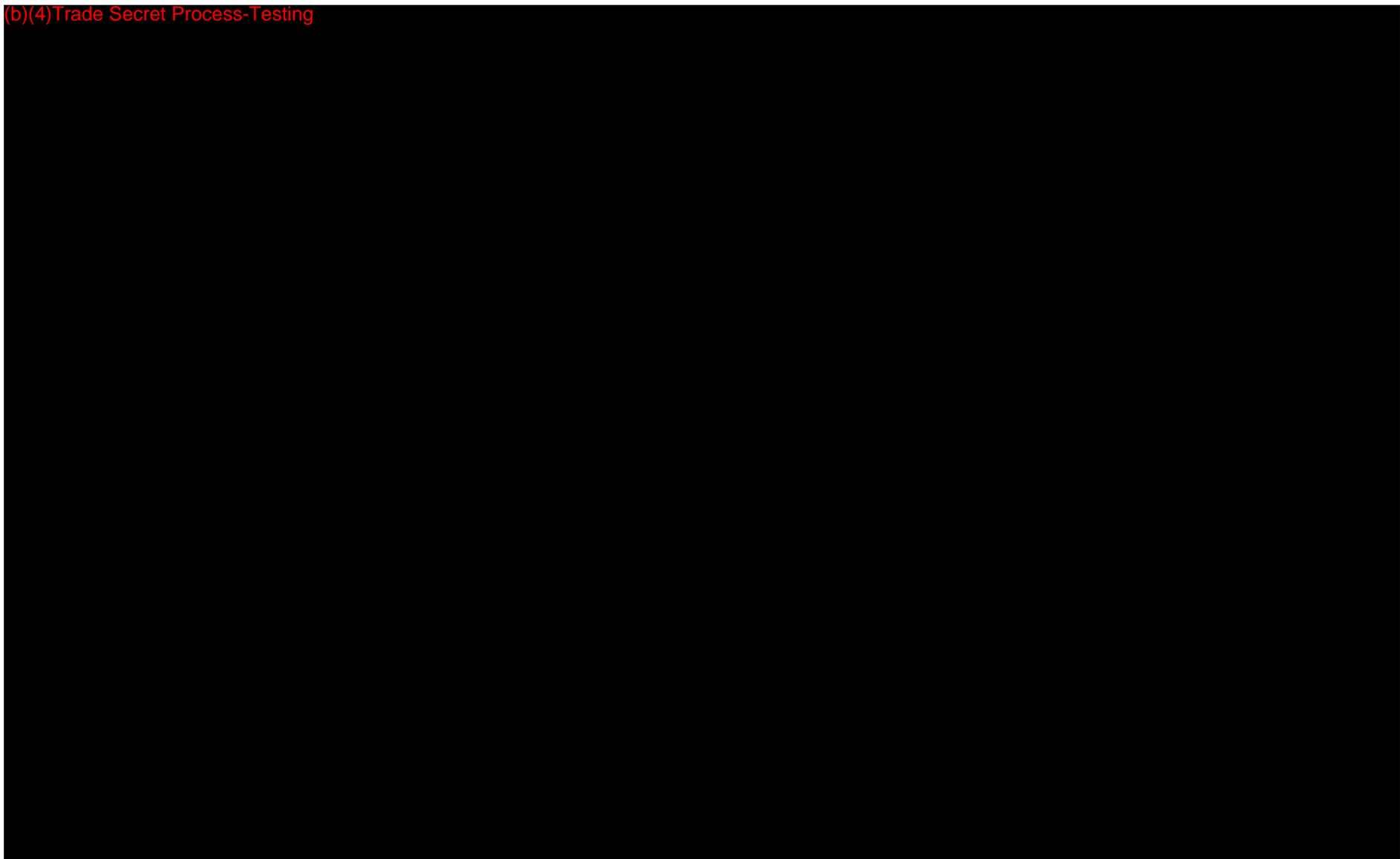
(b)(4) Trade Secret Process-Testing



(b)(4)Trade Secret Process-Testing

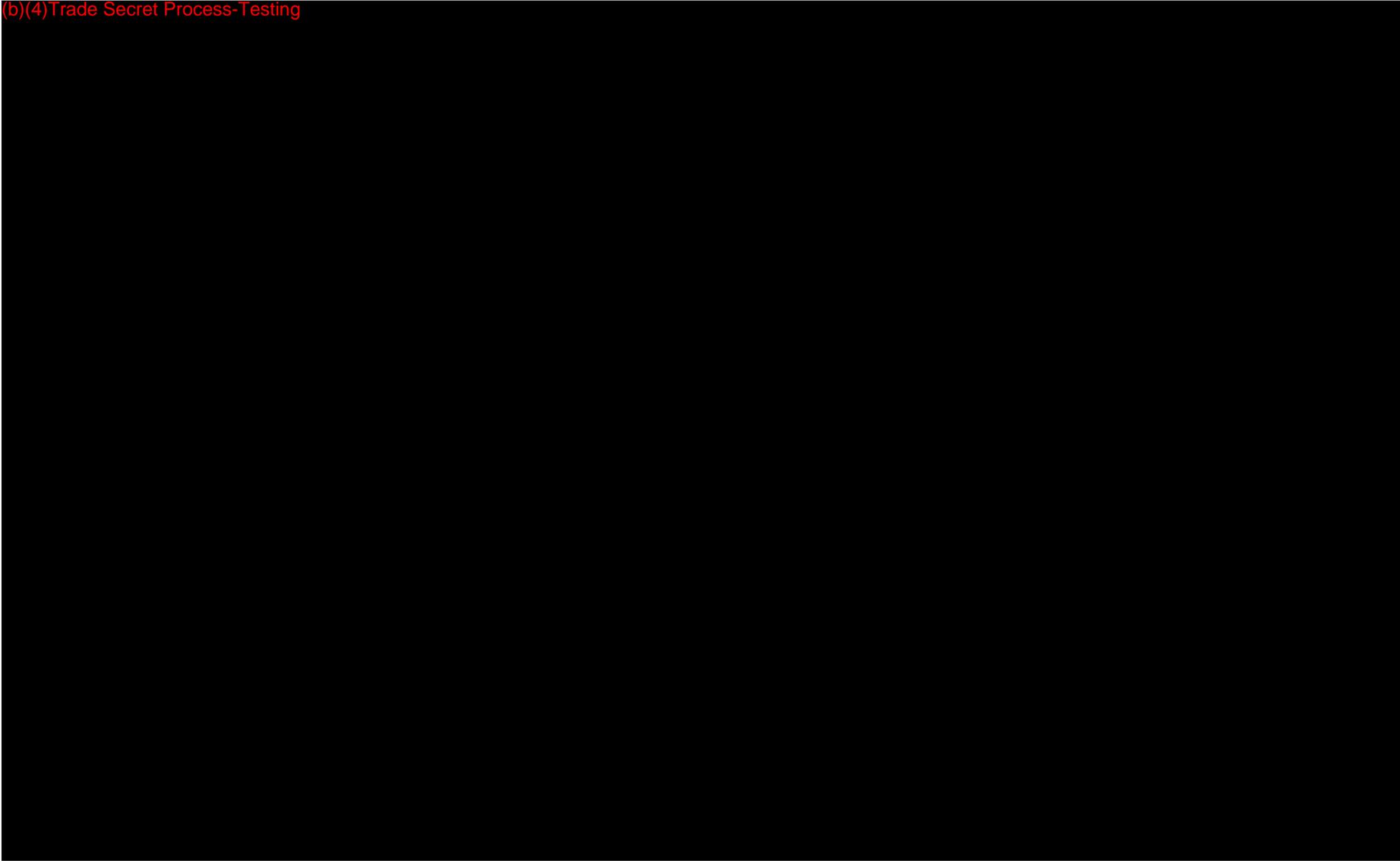


(b)(4)Trade Secret Process-Testing



Navilyst Medical, Inc.
NAMIC RCS, Abbreviated 510(k)
January 24, 2014

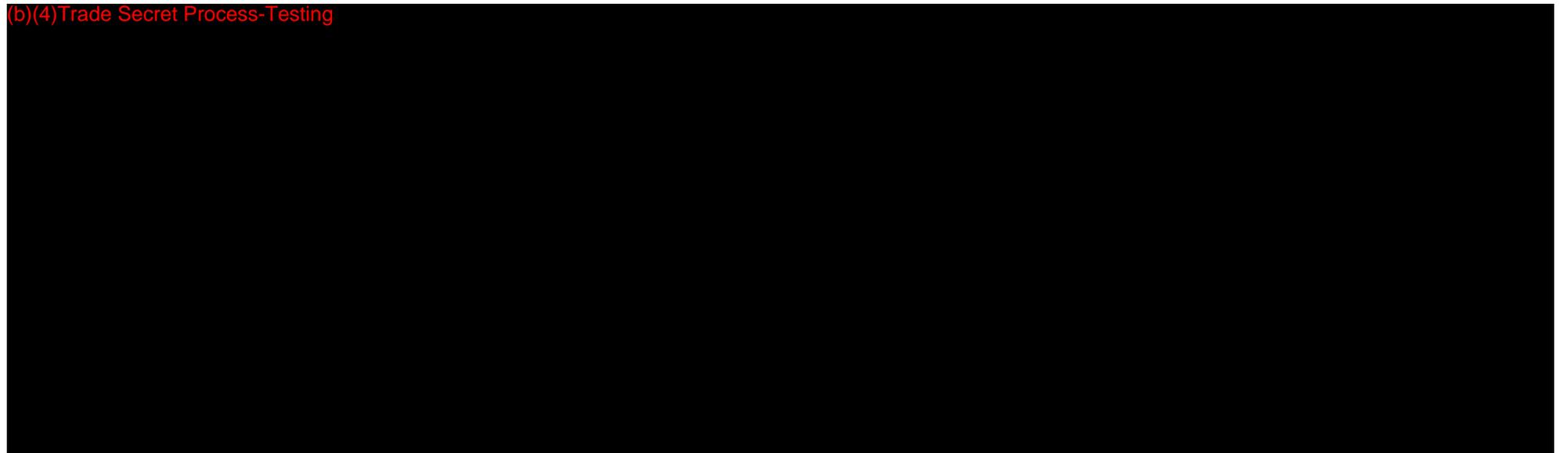
(b)(4)Trade Secret Process-Testing



(b)(4) Trade Secret Process-Testing



(b)(4)Trade Secret Process-Testing



SECTION 13

LABELING

*All labeling is provided in **Attachment 1**.

Proposed Labeling:

- Draft NAMIC RCS Directions for Use
- Draft NAMIC RCS Product Labels

Predicate **K113198** Labeling

- Directions for Use
- Product Labels

Predicate **K875196** Labeling:

- Directions for Use
- Product Labels

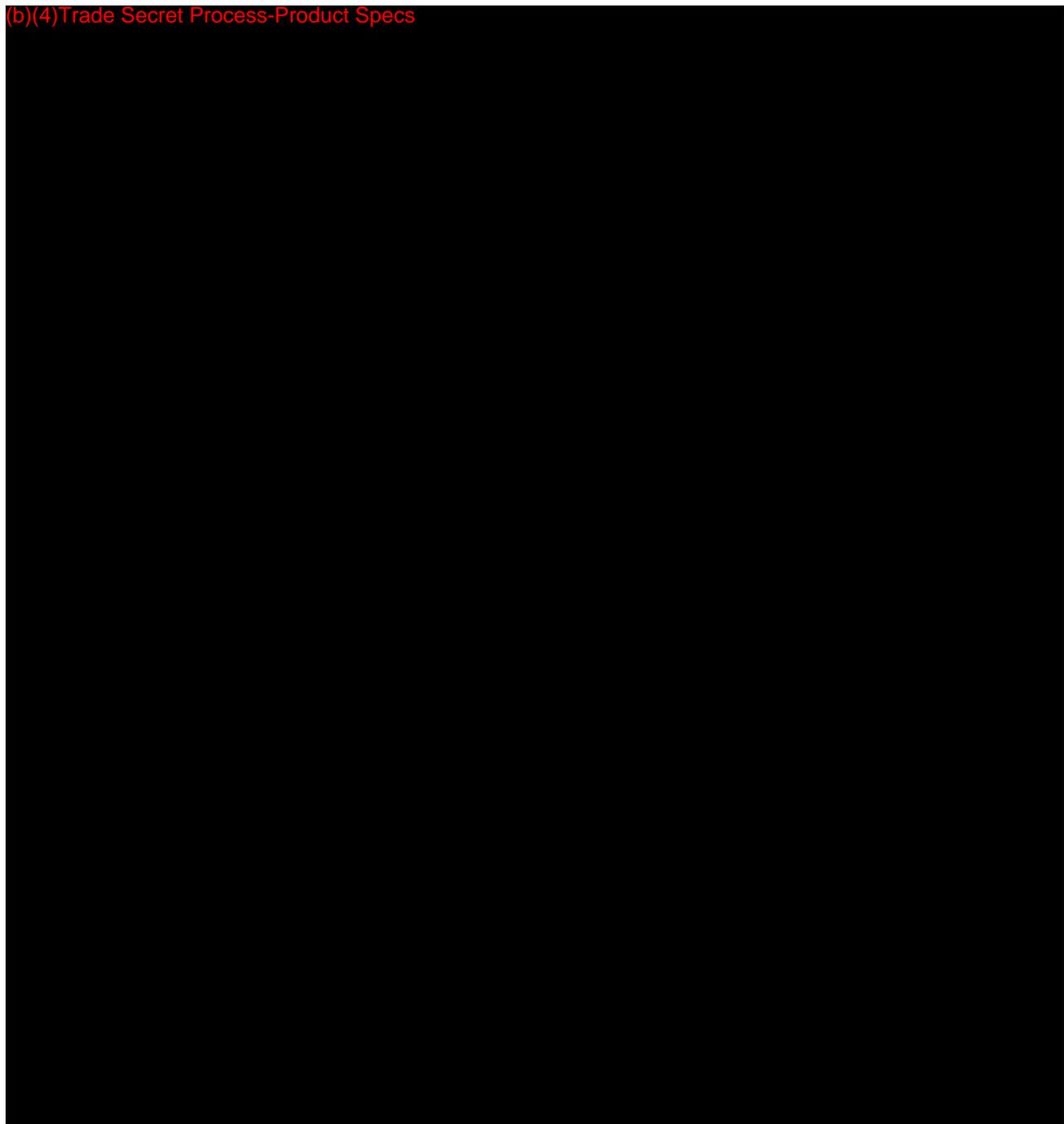
Navilyst Medical, Inc.
NAMIC RCS, Abbreviated 510(k)
January 24, 2014

SECTION 14

STERILIZATION AND SHELF LIFE

STERILIZATION

(b)(4)Trade Secret Process-Product Specs



PYROGENICITY

(b)(4)Trade Secret Process-Product Specs



SHELF LIFE

(b)(4)Trade Secret Process-Product Specs



ARRHENIUS EQUATION

Accelerated aging is based on the assumption that chemical reactions follow the Arrhenius reaction rate function. Based on modeling kinetics of materials, this function states that a 10°C increase or decrease in temperature of a homogenous process results in a 2x or 1/2x change, respectively, in the rate of a chemical reaction (Q_{10}). This applies to shelf life as the equation

$$t = \frac{T}{2^{\frac{(b-a)}{10}}}$$

where t is the time required for product to be in an elevated temperature, T is the shelf life period being sought or claimed, b is the elevated temperature being used (° C), and a the ambient storage temperature (° C) expected for standard product storage. This equation is a generalization that reaction rates of chemical processes double in rate for every 10°C increase in temperature.

SECTION 15

BIOCOMPATIBILITY

Biocompatibility

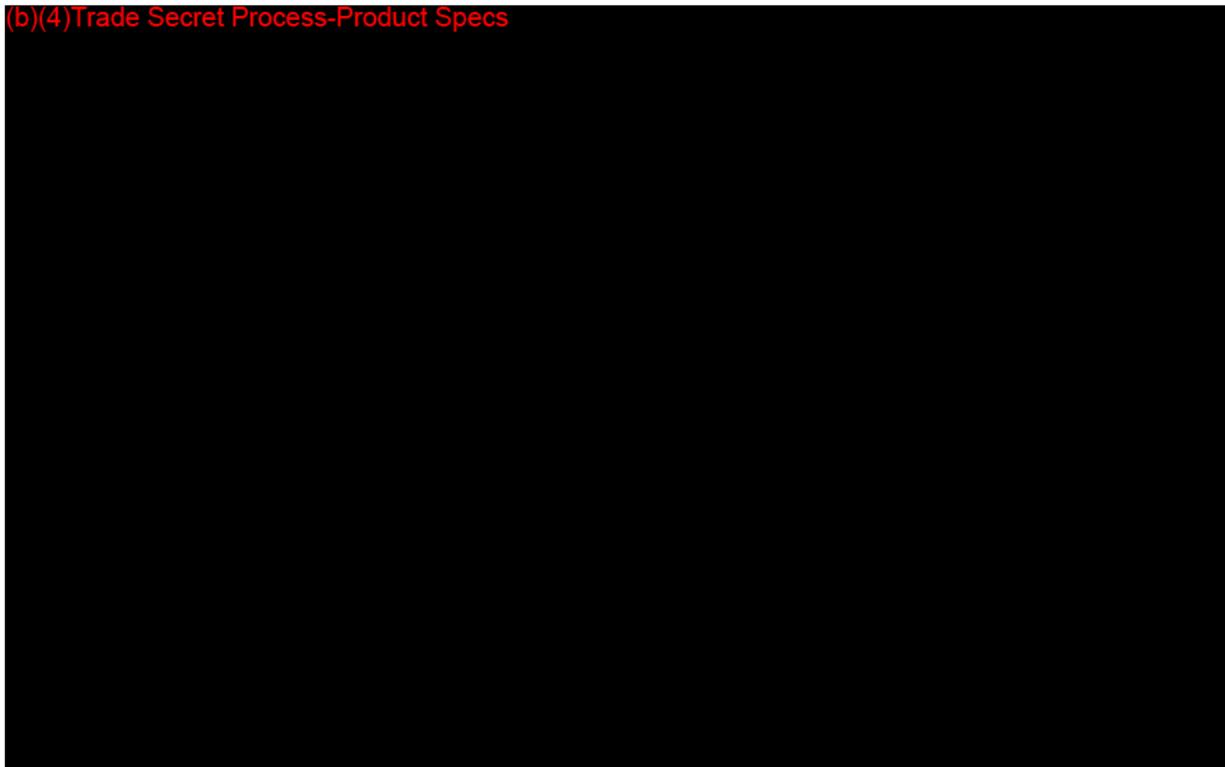
According to EN ISO 10993, the proposed NAMIC RCS syringes are classified as:

- Category: Externally Communicating
- Contact Duration: <24 hours
- Device Body Contact: Blood Path Indirect

Table #9 (b) (4)

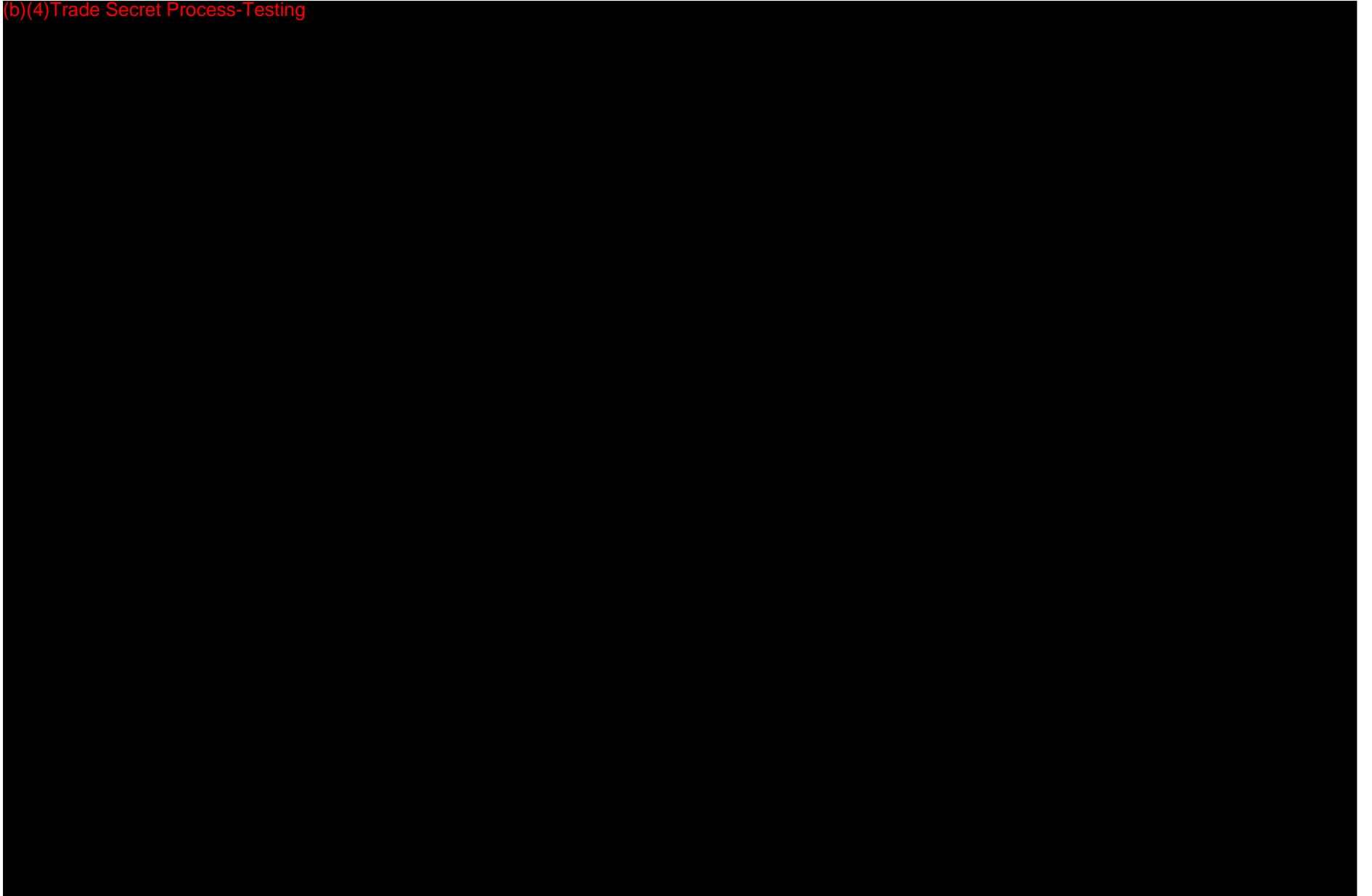


(b)(4)Trade Secret Process-Product Specs

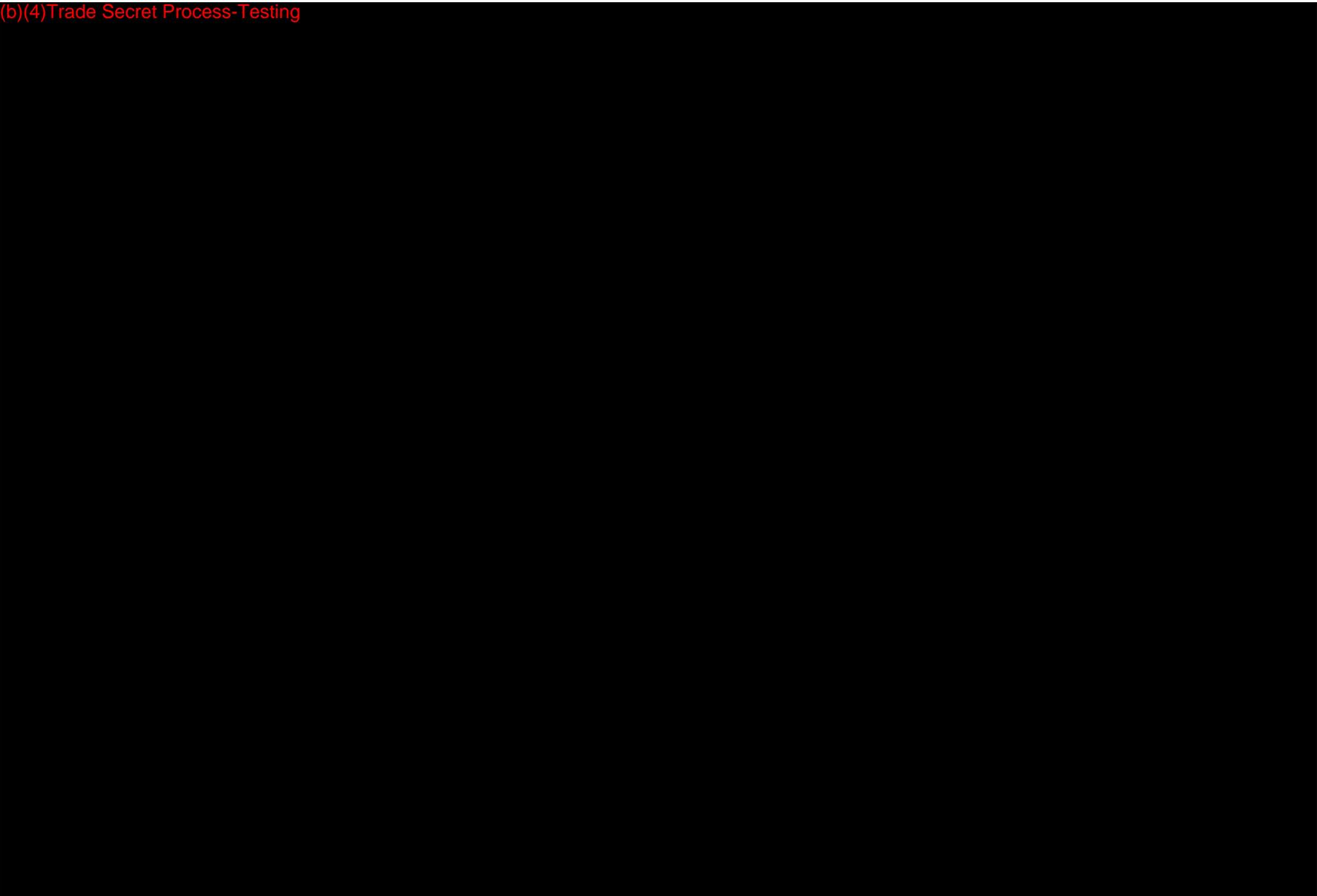


The results of the biocompatibility tests and assessments per EN ISO 10993 confirmed that the device is biocompatible for its intended use.

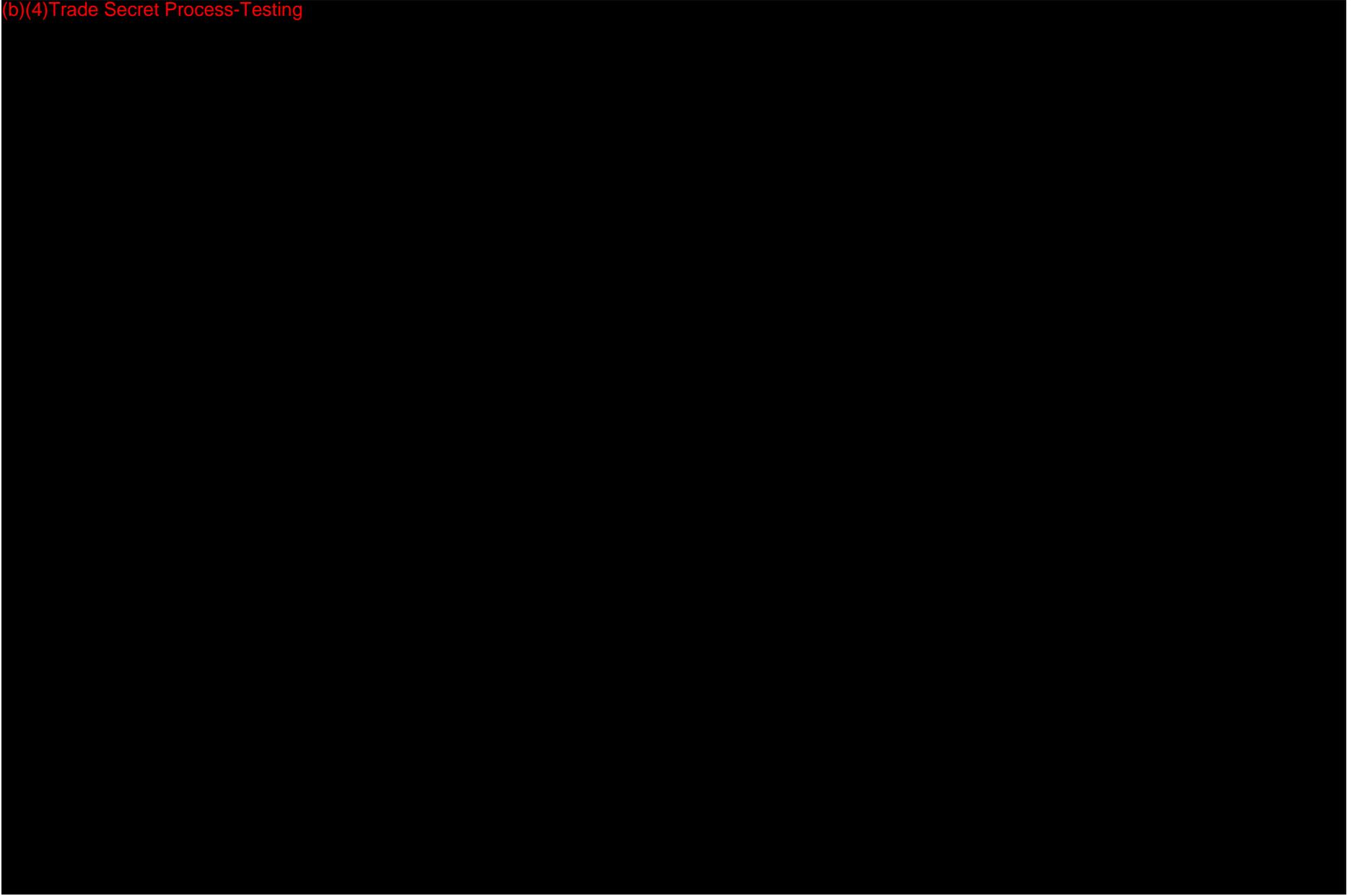
(b)(4) Trade Secret Process-Testing



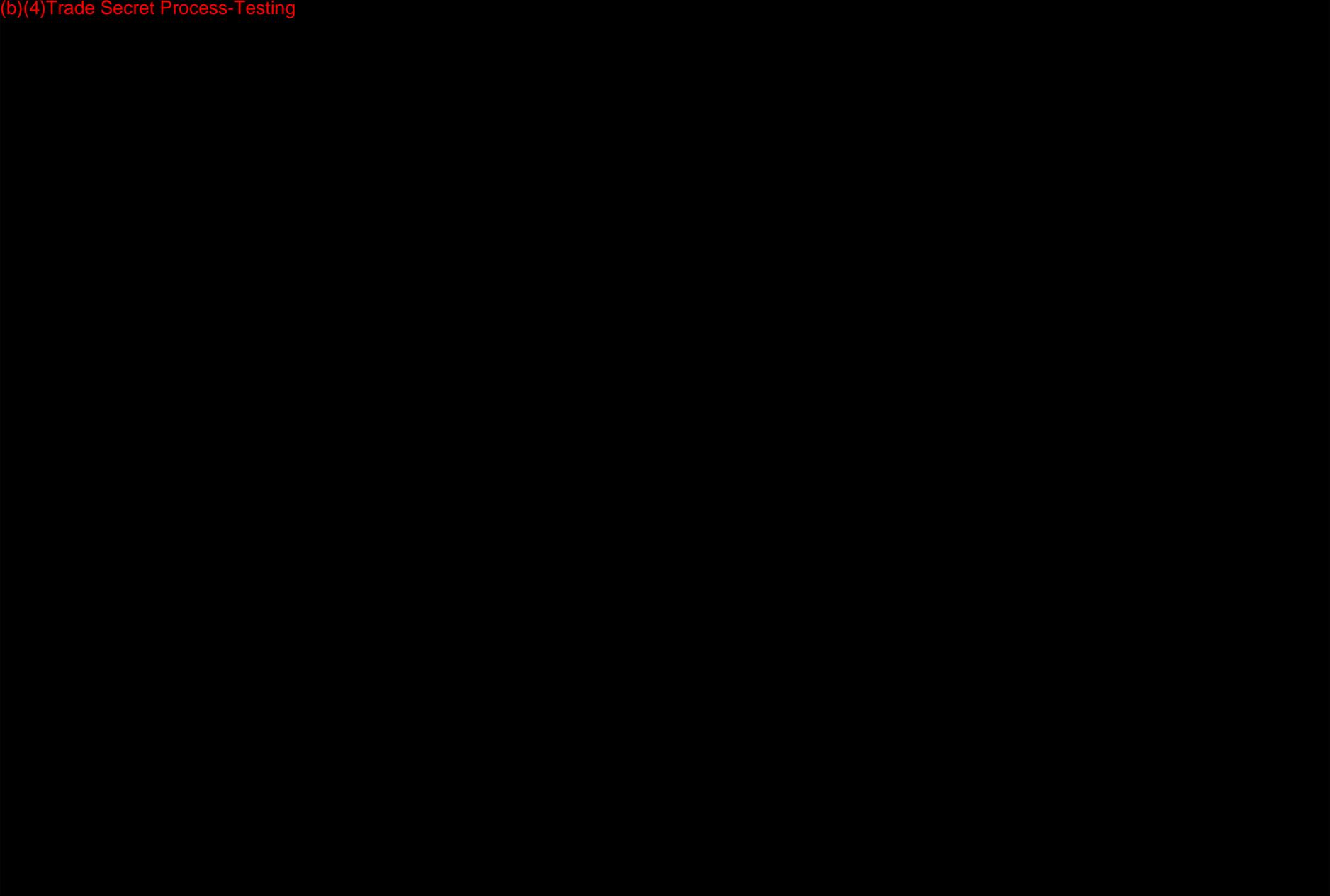
(b)(4) Trade Secret Process-Testing



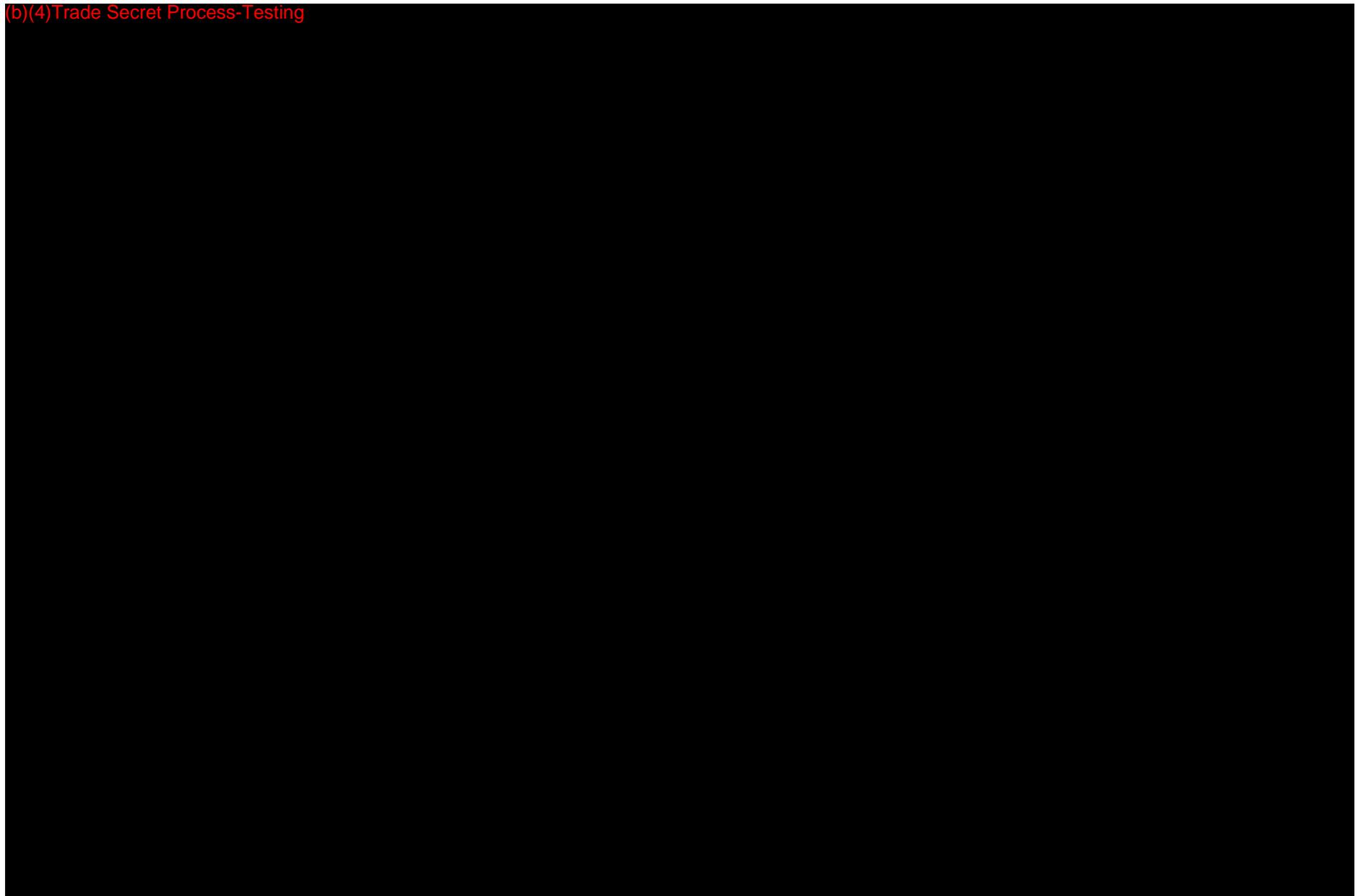
(b)(4) Trade Secret Process-Testing



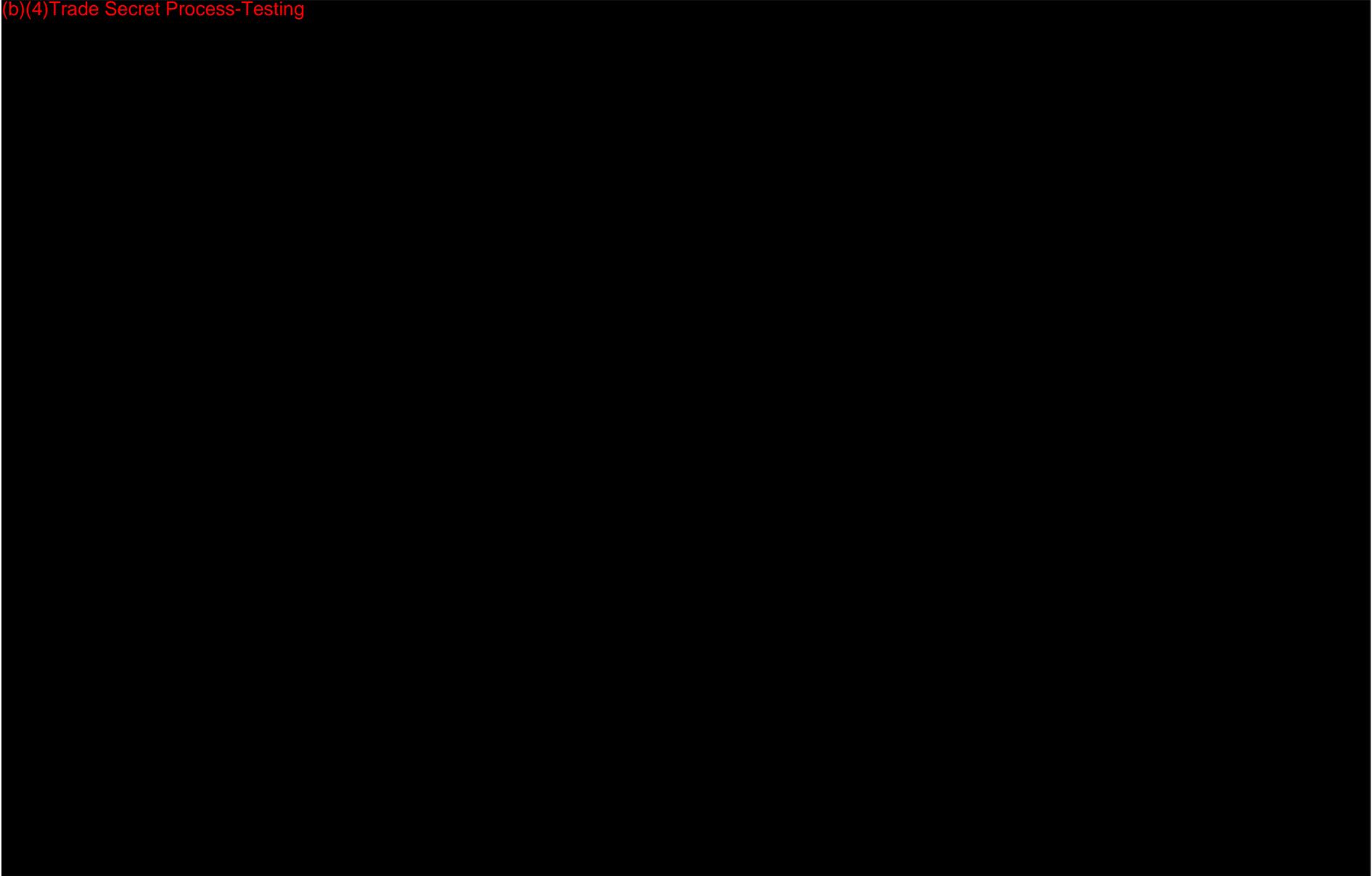
(b)(4) Trade Secret Process-Testing



(b)(4) Trade Secret Process-Testing



(b)(4) Trade Secret Process-Testing



SECTION 16

SOFTWARE

*The proposed device **DOES NOT** contain software.

SECTION 17

ELECTROMAGNETIC COMPATIBILITY AND SAFETY

*The proposed device **DOES NOT** contain electrical or metal components.

SECTION 18

DECLARATIONS OF CONFORMITY AND STANDARD DATA REPORT FORMS

A. STERILIZATION/MICROBIOLOGICAL

- Declaration of Conformity to Sterilization/Microbiological Standards
- Standards Data Reports for 510(k); FDA Form 3654
 - The proposed NAMIC RCS conforms to the following FDA recognized standards:
 - AAMI/ANSI/ISO 10993-7:2008/(R)2012 – “Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals”
 - AAMI/ANSI/ISO 11135-1:2007 – “Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices”
 - AAMI/ANSI/ISO 11138-1:2006/(R)2010 – “Sterilization of Health Care Products – Biological Indicators – Part 1: General Requirements”
 - AAMI/ANSI/ISO 11737-1:2006/(R)2011 – “Sterilization of Medical Devices – Microbiological Methods – Part 1: Determination of a Population of Microorganisms on Products”
 - AAMI/ANSI/ISO ST72:2011 – “Bacterial Endotoxins – Test Methods, Routine Monitoring, and Alternatives to Batch Testing”
 - The proposed NAMIC RCS conforms to the following voluntary standards:
 - AAMI/ANSI/ISO 11138-2:2009 – “Sterilization of Health Care Products – Biological Indicators – Part 2: Biological Indicators for Ethylene Oxide Sterilization Processes”
 - EN 556-1:2001 – “Sterilization of Medical Devices – Requirements for Medical Devices to be Designated “STERILE” – Part 1: Requirements for Terminally Sterilized Medical Devices”

B. BIOCOMPATIBILITY

- Declaration of Conformity to Biocompatibility Standards
- Standards Data Reports for 510(k); FDA Form 3654
 - The proposed NAMIC RCS conforms to the following FDA recognized standards:
 - AAMI/ANSI/ISO 10993-1: 2009 – “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process”
 - AAMI/ANSI/ISO 10993-5: 2009 – “Biological Evaluation of Medical Devices – Part 5: Tests for In-Vitro Cytotoxicity”
 - AAMI/ANSI/ISO 10993-10: 2010 – “Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity”
 - AAMI/ANSI/ISO 10993-11:2006/(R)2010 – “Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity”
 - AAMI/ANSI/ISO 10993-12: 2012 – “Biological Evaluation of medical devices – Part 12: Sample Preparation and Reference Materials”
 - USP 35-NF 30:2012 <151> – “Pyrogen Test”

- The proposed NAMIC RCS conforms to the following voluntary standards:
 - USP 35-NF 30:2012 <661> – “Containers – Plastics: Physiochemical Tests”
 - EN ISO 10993-4:2009 – “Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood”

C. PERFORMANCE TESTING

- Declaration of Conformity to Performance Standards
- Standards Data Reports for 510(k); FDA Form 3654
 - The proposed NAMIC RCS conforms to the following FDA recognized standards:
 - ISO 594-2:1998 – “Conical Fittings with 6% (Luer) Taper for Syringe, Needles, and Certain other Medical Equipment – Part 2: Lock Fittings”
 - ISO 7886-1:1997 – “Sterile Hypodermic Syringes for Single Use, Syringes for Manual Use”

D. PACKAGING

- Declaration of Conformity to Packaging Standards
- Standards Data Reports for 510(k); FDA Form 3654
 - The proposed NAMIC RCS conforms to the following FDA recognized standards:
 - AAMI/ANSI/ISO 11607-1: 2006 – “Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems, 3rd Edition”
 - AAMI/ANDI/ISO 11607-2: 2006 – “Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes, 1st Edition”
 - ASTM F88/F88M:2009 – “Standard Test Method for Seal Strength of Flexible Barrier Materials”
 - ASTM F1980:2007 – “Standard Guide for Accelerated Aging of Sterile Medical Device Packages”
 - ASTM F1929-98:2004 – “Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration”
 - ASTM F1886/F1886M:2009 – “Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection”
 - The proposed NAMIC RCS conforms to the following voluntary standards:
 - ISTA 2A:2011 – “Performance Test for Packaged-Products 150 lb (68kg) or Less”

A. Sterilization and Microbiological

The proposed NAMIC RCS conforms to the following FDA recognized standards:

- AAMI/ANSI/ISO 10993-7:2008/(R)2012 – “Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals”
- AAMI/ANSI/ISO 11135-1:2007 – “Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices”
- AAMI/ANSI/ISO 11138-1:2006/(R)2010 – “Sterilization of Health Care Products – Biological Indicators – Part 1: General Requirements”
- AAMI/ANSI/ISO 11737-1:2006/(R)2011 – “Sterilization of Medical Devices – Microbiological Methods – Part 1: Determination of a Population of Microorganisms on Products”
- AAMI/ANSI/ISO ST72:2011 – “Bacterial Endotoxins – Test Methods, Routine Monitoring, and Alternatives to Batch Testing”

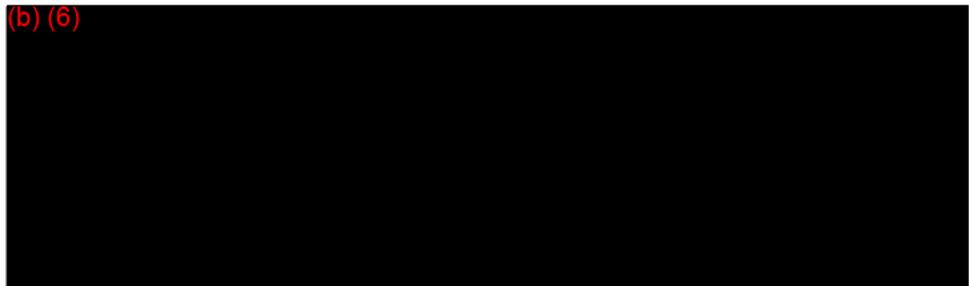
The proposed NAMIC RCS conforms to the following voluntary standards:

- AAMI/ANSI/ISO 11138-2:2009 – “Sterilization of Health Care Products – Biological Indicators – Part 2: Biological Indicators for Ethylene Oxide Sterilization Processes”
- EN 556-1:2001 – “Sterilization of Medical Devices – Requirements for Medical Devices to be Designated “STERILE” – Part 1: Requirements for Terminally Sterilized Medical Devices”

I certify that, in my capacity as Senior Vice President of Quality and Regulatory Affairs of Navilyst Medical Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no information has been omitted.

In addition, to the best of my knowledge, this device complies as indicated with the FDA recognized and voluntary standards identified above.

(b) (6)



Department of Health and Human Services
 Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
 (To be filled in by applicant)

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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI/ANSI/ISO 11737-1 Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products (2006[R]2011)

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number ³ # 14-227

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
 If yes, report these deviations or adaptations in the summary report table.

Were there exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

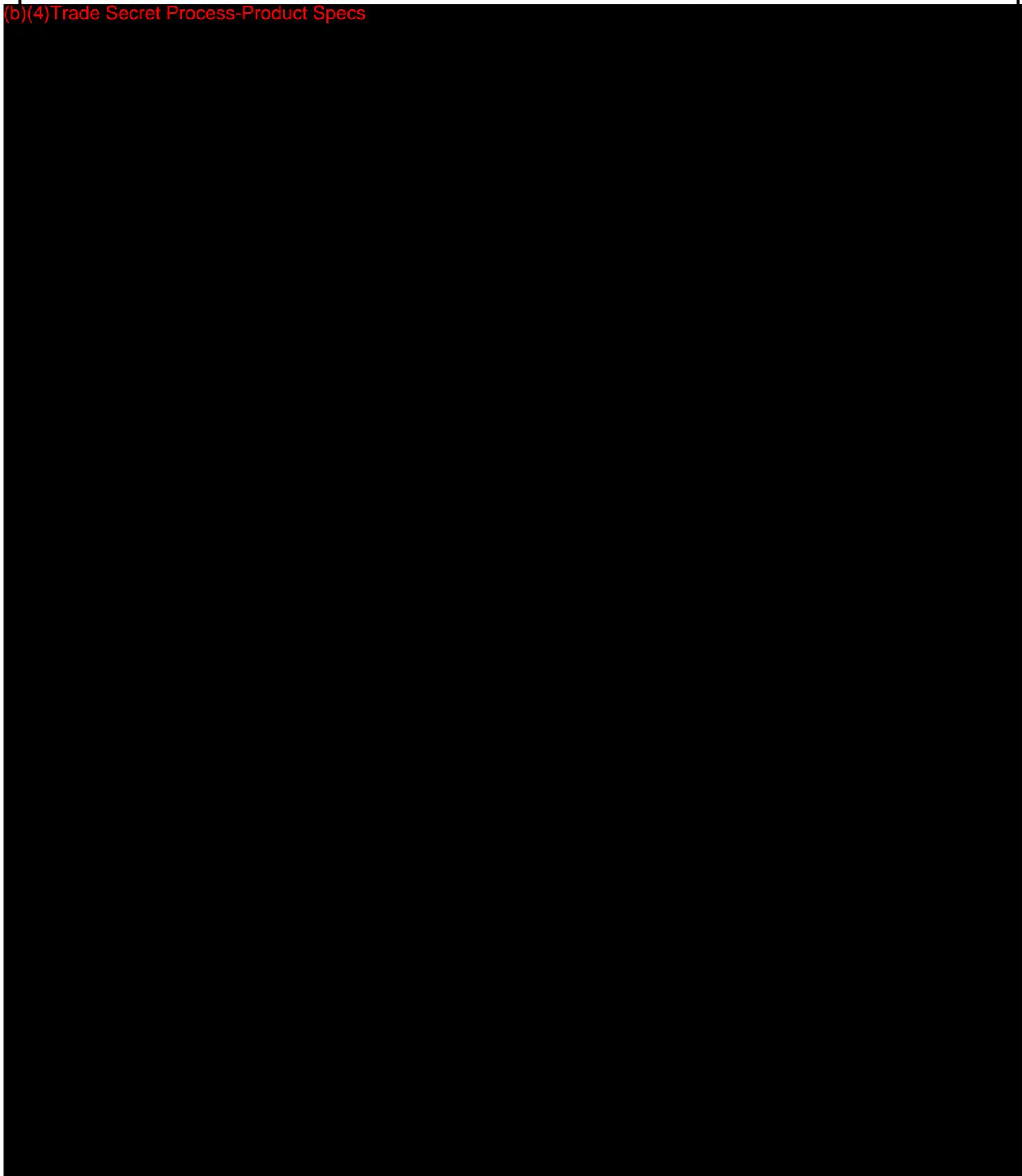
**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

AAMI/ANSI/ISO 11737-1 Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products (2006[R]2011)

CONFORMANCE WITH STANDARD SECTIONS*

(b)(4)Trade Secret Process-Product Specs



Department of Health and Human Services
 Food and Drug Administration
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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

EN ISO 11138-2 Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes (2009) VOLUNTARY

Please answer the following questions	Yes	No
Is this standard recognized by FDA ² ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
FDA Recognition number ³	N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were there exclusions from the standard? If yes, report these exclusions in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510(k)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Title of guidance: _____		

<p>¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p>² Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</p> <p>³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and</p>	<p>address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.</p> <p>⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁶ The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</p>
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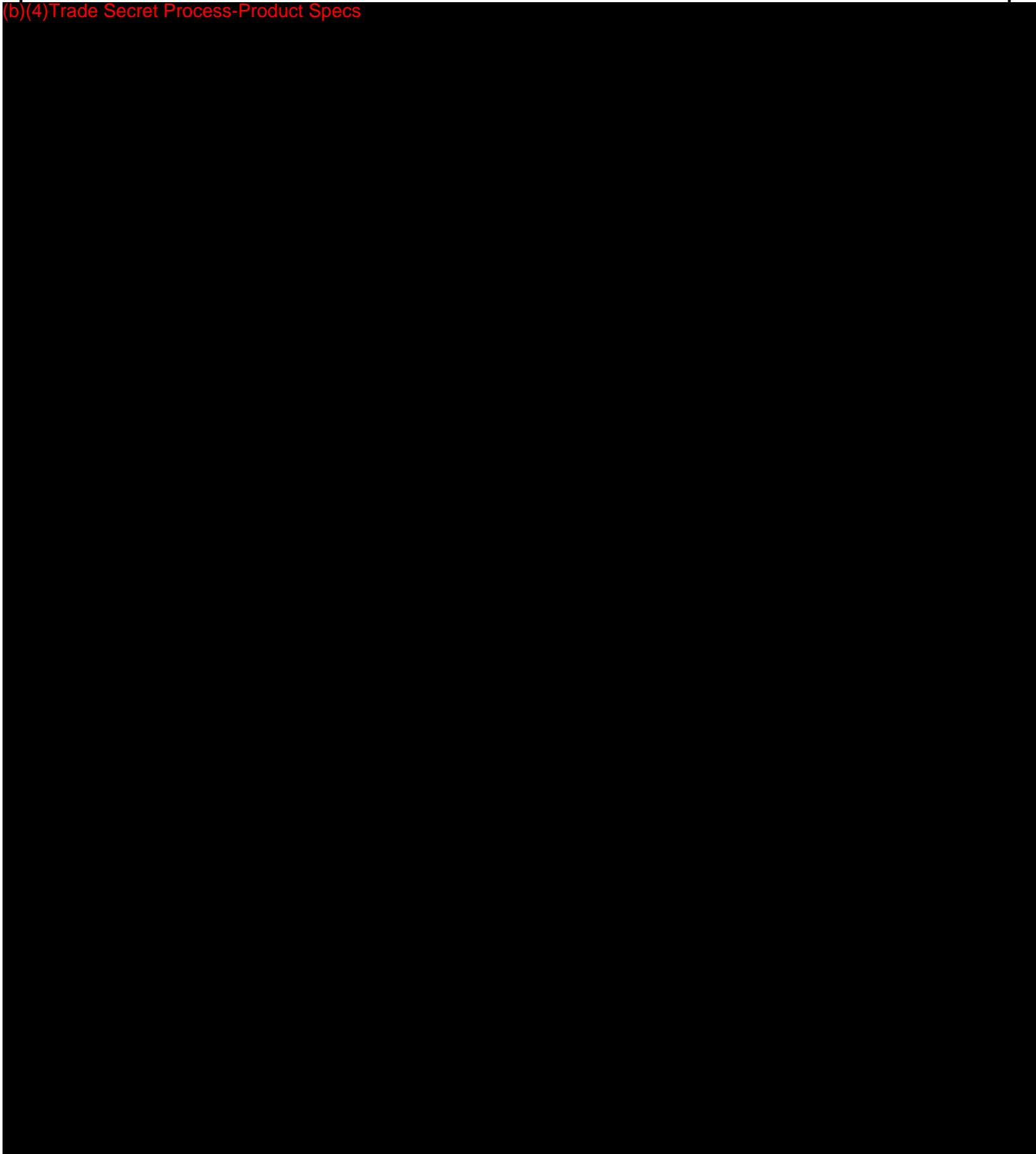
**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

EN ISO 11138-2 Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes (2009) VOLUNTARY

CONFORMANCE WITH STANDARD SECTIONS*

(b)(4)Trade Secret Process-Product Specs



Department of Health and Human Services
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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI/ANSI/ISO 11138-1 Sterilization of health care products – Biological indicators – Part 1: General requirements (2006[R]2010)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 14-296

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

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 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
 If yes, report these deviations or adaptations in the summary report table.

Were there exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: _____

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² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

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⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

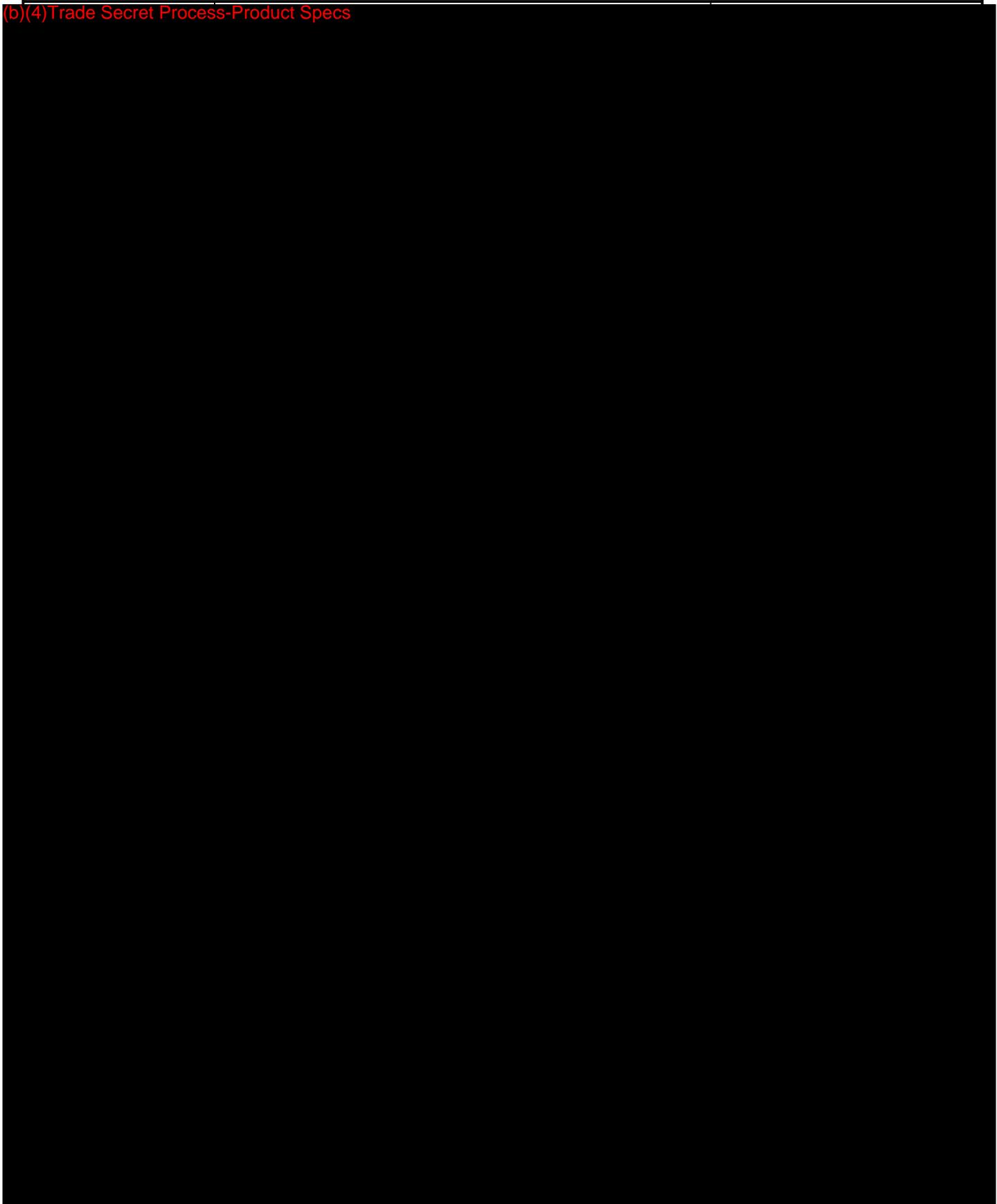
**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

AAMI/ANSI/ISO 11138-1 Sterilization of health care products – Biological indicators – Part 1: General requirements (2006[R]2010)

CONFORMANCE WITH STANDARD SECTIONS*

(b)(4)Trade Secret Process-Product Specs



Department of Health and Human Services
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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI/ANSI/ISO 11135-1 Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (2007)

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number ³ # 14-228

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: ANSI/AAMI/ISO TIR 11135-2 Sterilization of health care products - Ethylene oxide - Part 2: Guidance on the application of ANSI/AAMI/ISO 11135-1 (2008)

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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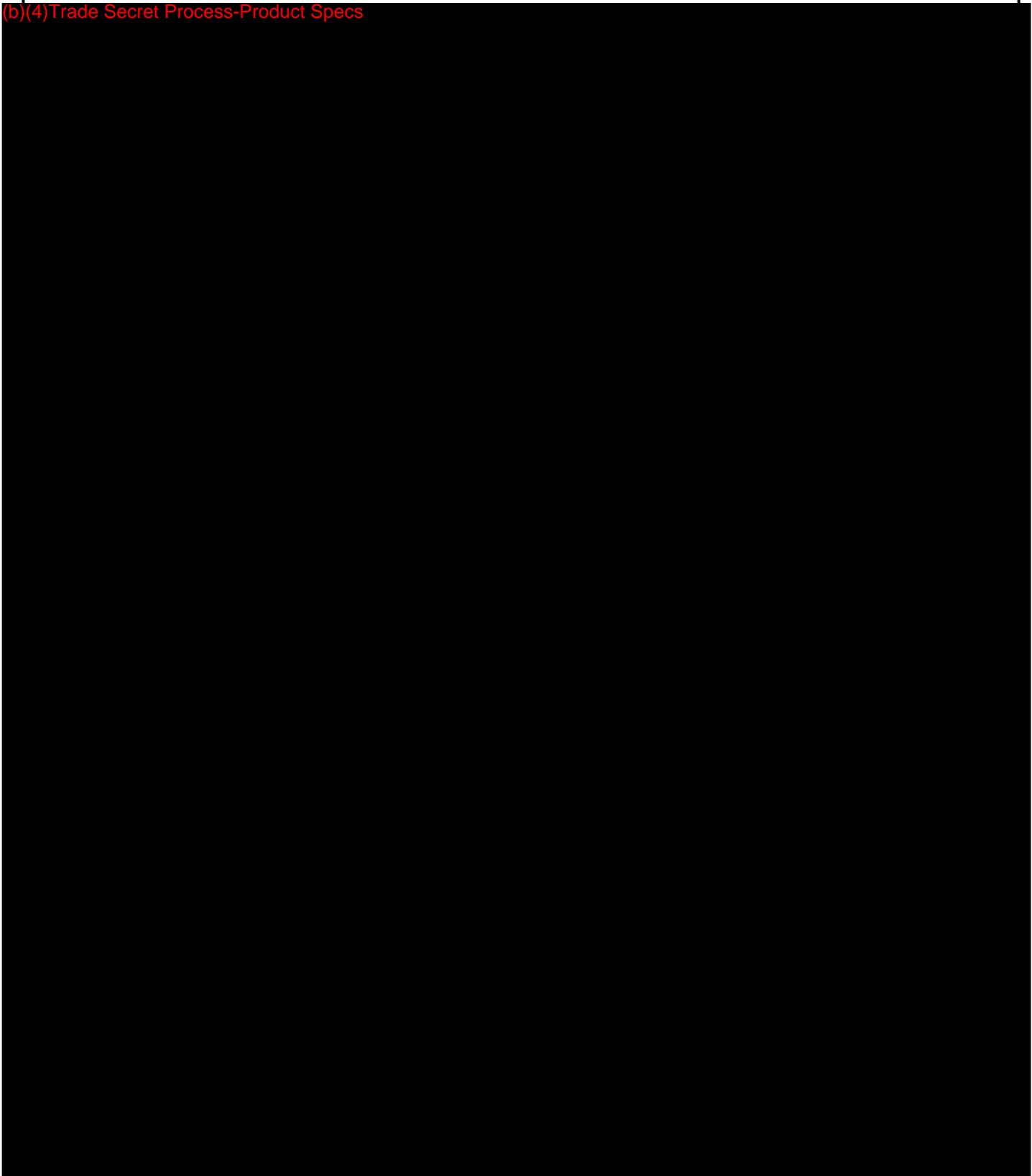
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SUMMARY REPORT TABLE**

STANDARD TITLE

AAMI/ANSI/ISO 11135-1 Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (2007)

CONFORMANCE WITH STANDARD SECTIONS*

(b)(4) Trade Secret Process-Product Specs



Department of Health and Human Services
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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI/ANSI/ISO 10993-7 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals (2008[R]2012)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 14-278

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
 If yes, report these deviations or adaptations in the summary report table.

Were there exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: _____

<p>¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p>² Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</p> <p>³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and</p>	<p>address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.</p> <p>⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁶ The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</p>
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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

AAMI/ANSI/ISO 10993-7 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals (2008[R]2012)

CONFORMANCE WITH STANDARD SECTIONS*

(b)(4)Trade Secret Process-Product Specs

Department of Health and Human Services
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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

EN 556-1 Sterilization of medical devices – Requirements for medical devices to be designated “STERILE” – Part 1: Requirements for terminally sterilized medical devices (2001) VOLUNTARY

Please answer the following questions	Yes	No
Is this standard recognized by FDA ² ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
FDA Recognition number ³	N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were there exclusions from the standard? If yes, report these exclusions in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510(k)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Title of guidance: _____		

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

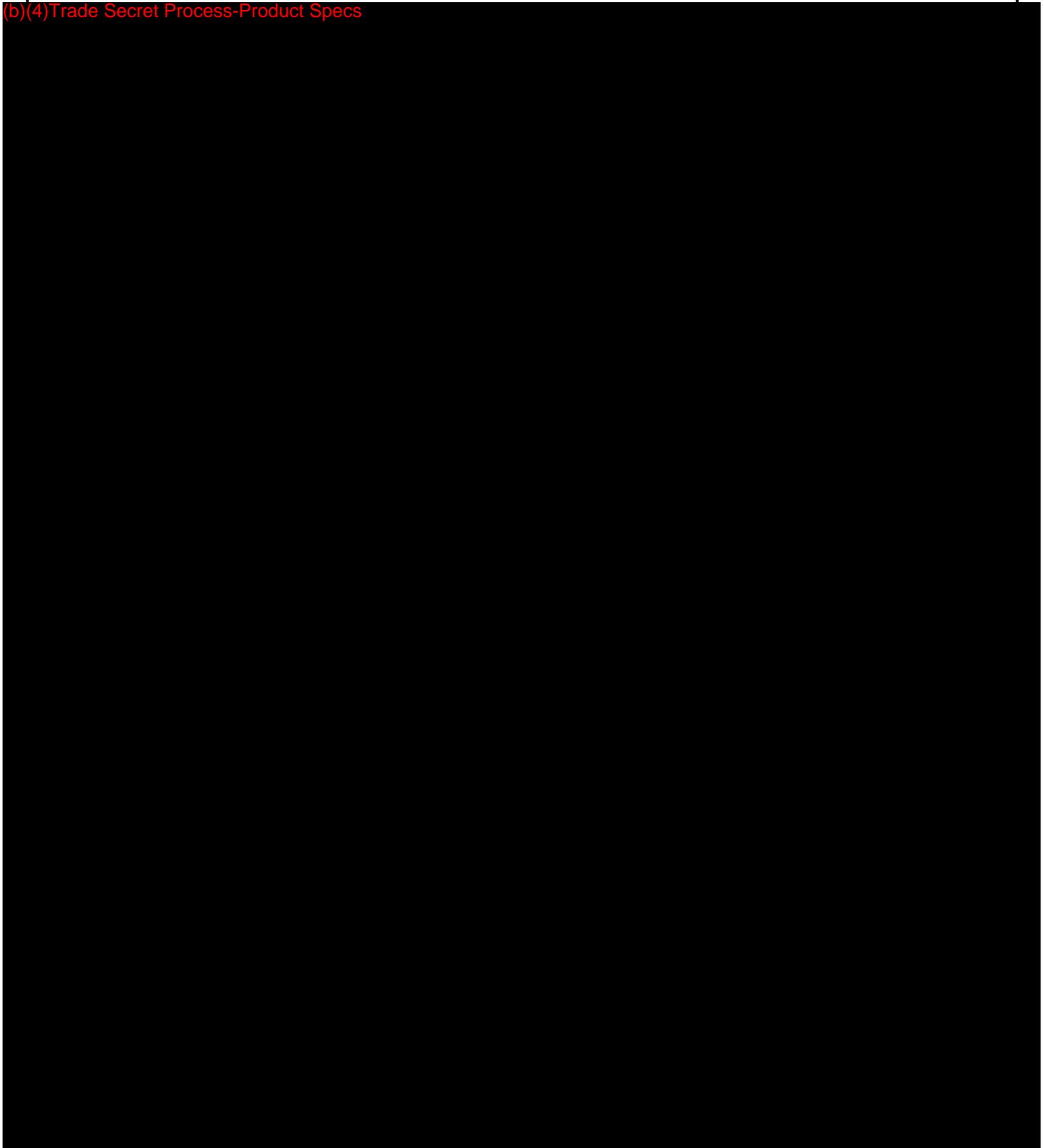
**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

EN 556-1 Sterilization of medical devices – Requirements for medical devices to be designated “STERILE” – Part 1: Requirements for terminally sterilized medical devices (2001) VOLUNTARY

CONFORMANCE WITH STANDARD SECTIONS*

(b)(4) Trade Secret Process-Product Specs



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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI/ANSI ST72 Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing (2011)

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number ³ # 14-360

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: USP 35-NF 30 <85> Bacterial Endotoxins Test (2012), USP 35-NF 30 <161> Transfusion and Infusion Assemblies and Similar Medical Devices (2012), and Guidance for Industry Pyrogens and Endotoxins Testing: Questions and Answers 2012) _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

AAMI/ANSI ST72 Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing (2011)

CONFORMANCE WITH STANDARD SECTIONS*

(b)(4)Trade Secret Process-Product Specs

B. Biocompatibility

The proposed NAMIC RCS conforms to the following FDA recognized standards:

- AAMI/ANSI/ISO 10993-1: 2009 – “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process”
- AAMI/ANSI/ISO 10993-5: 2009 – “Biological Evaluation of Medical Devices – Part 5: Tests for In-Vitro Cytotoxicity”
- AAMI/ANSI/ISO 10993-10: 2010 – “Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity”
- AAMI/ANSI/ISO 10993-11:2006/(R)2010 – “Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity”
- AAMI/ANSI/ISO 10993-12: 2012 – “Biological Evaluation of medical devices – Part 12: Sample Preparation and Reference Materials”
- USP 35-NF 30:2012 <151> – “Pyrogen Test”

The proposed NAMIC RCS conforms to the following voluntary standards:

- USP 35-NF 30:2012 <661> – “Containers – Plastics: Physiochemical Tests”
- EN ISO 10993-4:2009 – “Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood”

I certify that, in my capacity as Senior Vice President of Quality and Regulatory Affairs of Navilyst Medical Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no information has been omitted.

In addition, to the best of my knowledge, this device complies as indicated with the FDA recognized and voluntary standards identified above.

(b) (6)



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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

USP 35-NF 30 <661> Containers – Plastics: Physicochemical Tests (2012)
 VOLUNTARY

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ N/A

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

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Were deviations or adaptations made beyond what is specified in the FDA SIS?
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Were there exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: _____

<p>¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p>² Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</p> <p>³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and</p>	<p>address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.</p> <p>⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁶ The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</p>
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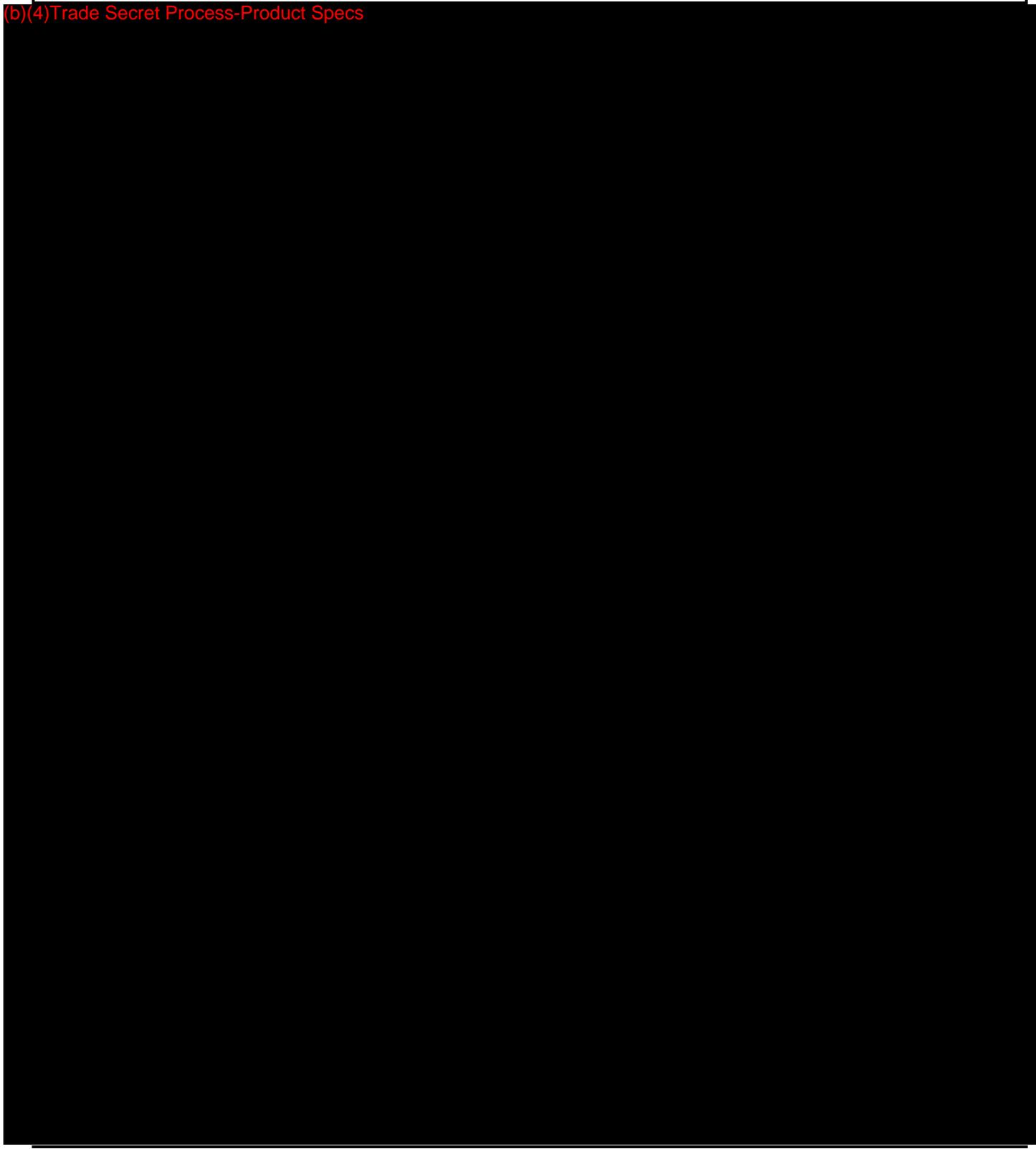
**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

USP 35-NF 30 <661> Containers – Plastics: Physicochemical Tests (2012)
VOLUNTARY

CONFORMANCE WITH STANDARD SECTIONS*

(b)(4)Trade Secret Process-Product Specs



Department of Health and Human Services
 Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
 (To be filled in by applicant)

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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

USP 35-NF 30 <151> Pyrogen Test (2012)

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number ³ # 14-369

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
 If yes, report these deviations or adaptations in the summary report table.

Were there exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: ANSI/AAMI ST72 Bacterial Endotoxins – Test Methods– Routine Monitoring, and Alternatives to Batch Testing (2011), USP 35-NF30 <85> Bacterial Endotoxins Test (2012), USP35-NF30 <161> Transfusion and Infusion Assemblies and Similar Medical Devices (2012), Guidance for Industry Pyrogens and Endotoxins Testing: Questions and Answers (2012)

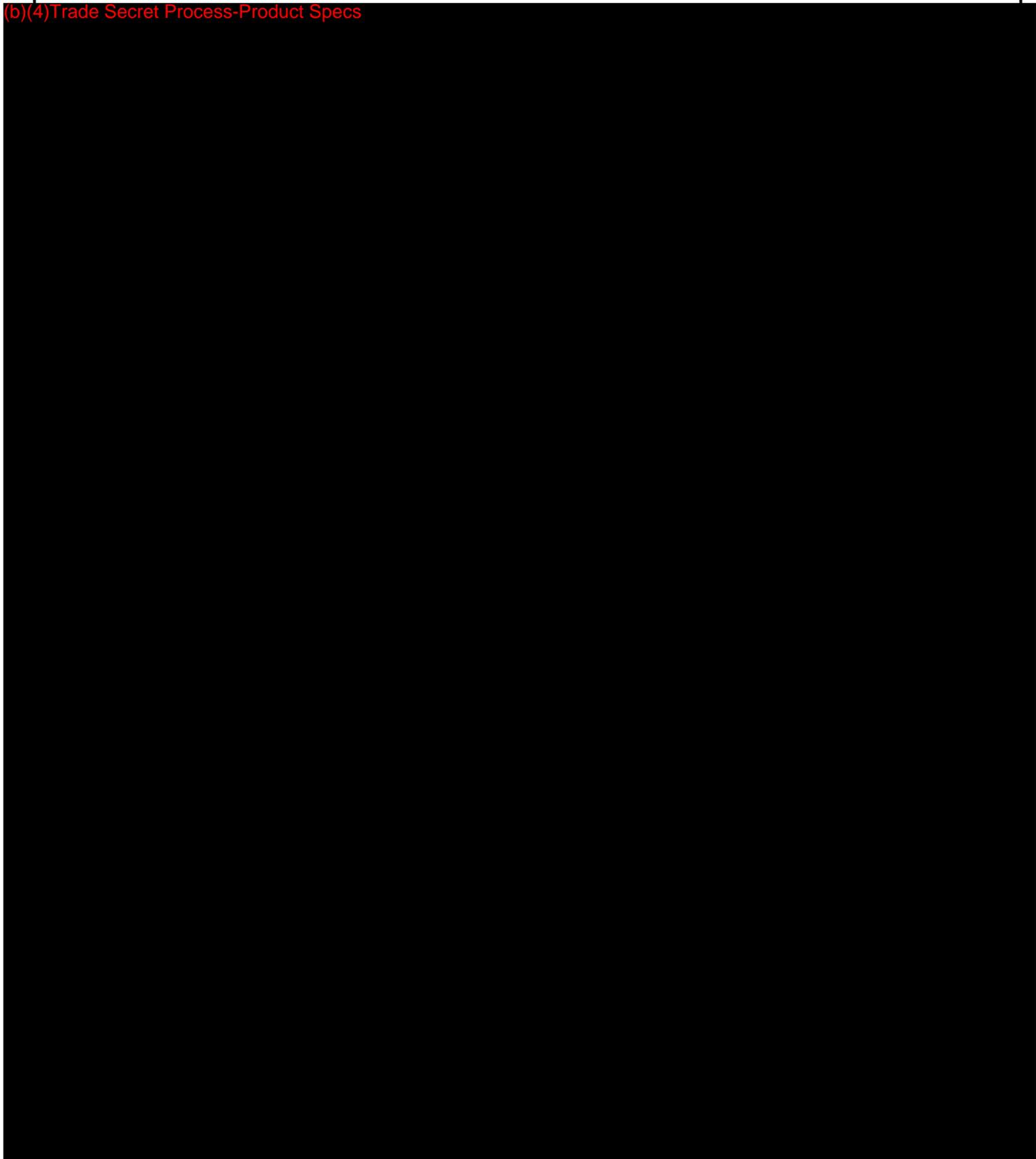
- ¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]
- ² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>
- ³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>
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- ⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>
- ⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

USP 35-NF 30 <151> Pyrogen Test (2012)

(b)(4)Trade Secret Process-Product Specs



Department of Health and Human Services
Food and Drug Administration
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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI/ANSI/ISO 10993-12 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials (2012)

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number ³ # 2-198

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: FDA Blue Book Memorandum G95-1 (1995) and FDA Draft Guidance Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" (2013)

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

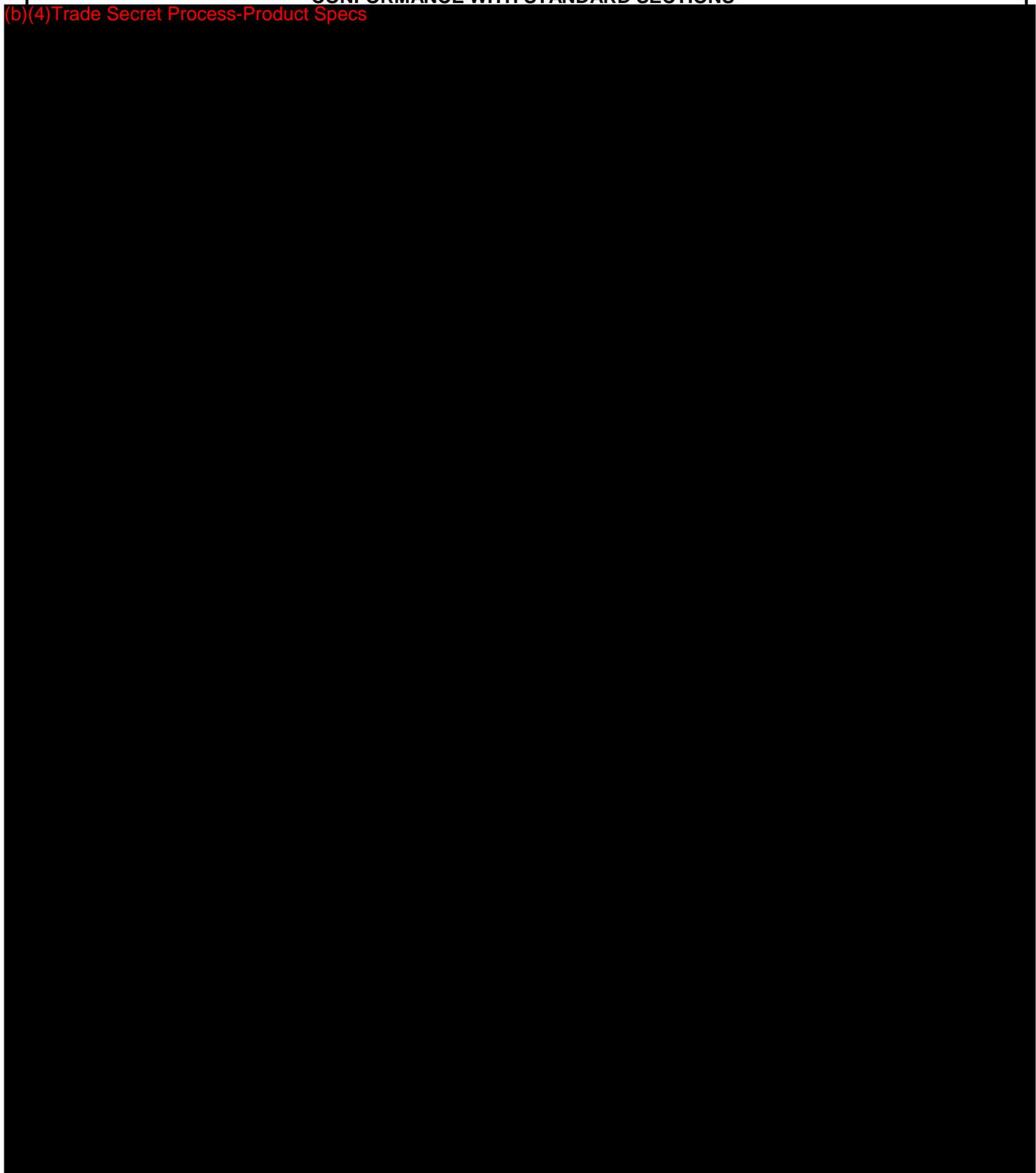
**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

AAMI/ANSI/ISO 10993-12 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials (2012)

CONFORMANCE WITH STANDARD SECTIONS*

(b)(4)Trade Secret Process-Product Specs



Department of Health and Human Services
Food and Drug Administration
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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI/ANSI/ISO 10993-11 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity (2006/[R]2010)

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number ³ # 2-118

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: AAMI/ANSI/ISO 10993-12 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials (2007) and FDA Blue Book Memorandum G95-1 (1995)

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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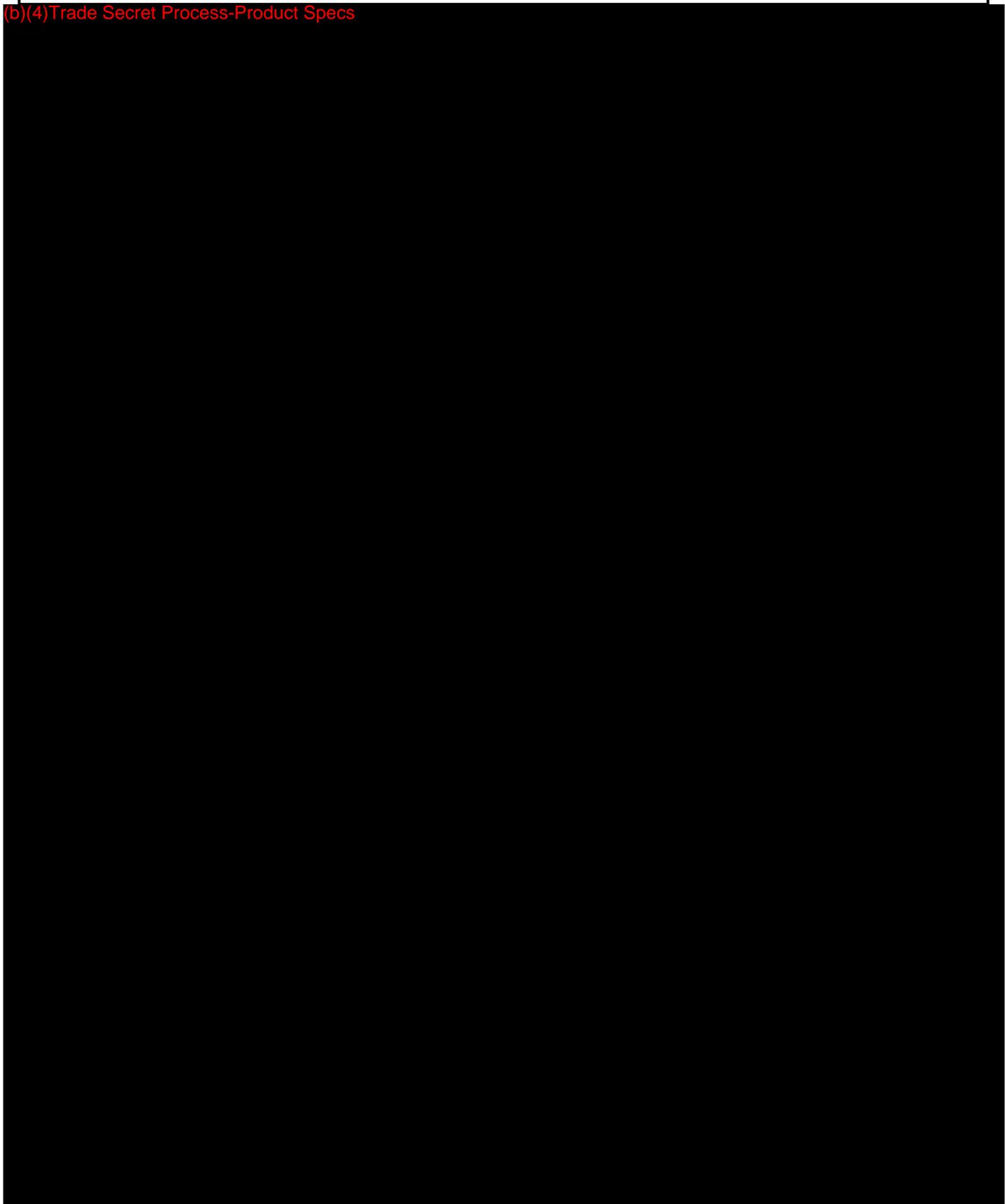
**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

AAMI/ANSI/ISO 10993-11 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity (2006/[R]2010)

CONFORMANCE WITH STANDARD SECTIONS*

(b)(4)Trade Secret Process-Product Specs





Department of Health and Human Services
 Food and Drug Administration
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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI/ANSI/ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization (2010)

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number ³ # 2-173

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
 If yes, report these deviations or adaptations in the summary report table.

Were there exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: AAMI/ANSI/ISO 10993-12 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials (2007) and FDA Blue Book Memorandum G95-1 (1995)

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

AAMI/ANSI/ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization (2010)

CONFORMANCE WITH STANDARD SECTIONS*

(b)(4) Trade Secret Process-Product Specs

Department of Health and Human Services
 Food and Drug Administration
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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI/ANSI/ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity (2009)

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number ³ # 2-153

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
 If yes, report these deviations or adaptations in the summary report table.

Were there exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: AAMI/ANSI/ISO 10993-12 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials (2007) and FDA Blue Book Memorandum G95-1 (1995)

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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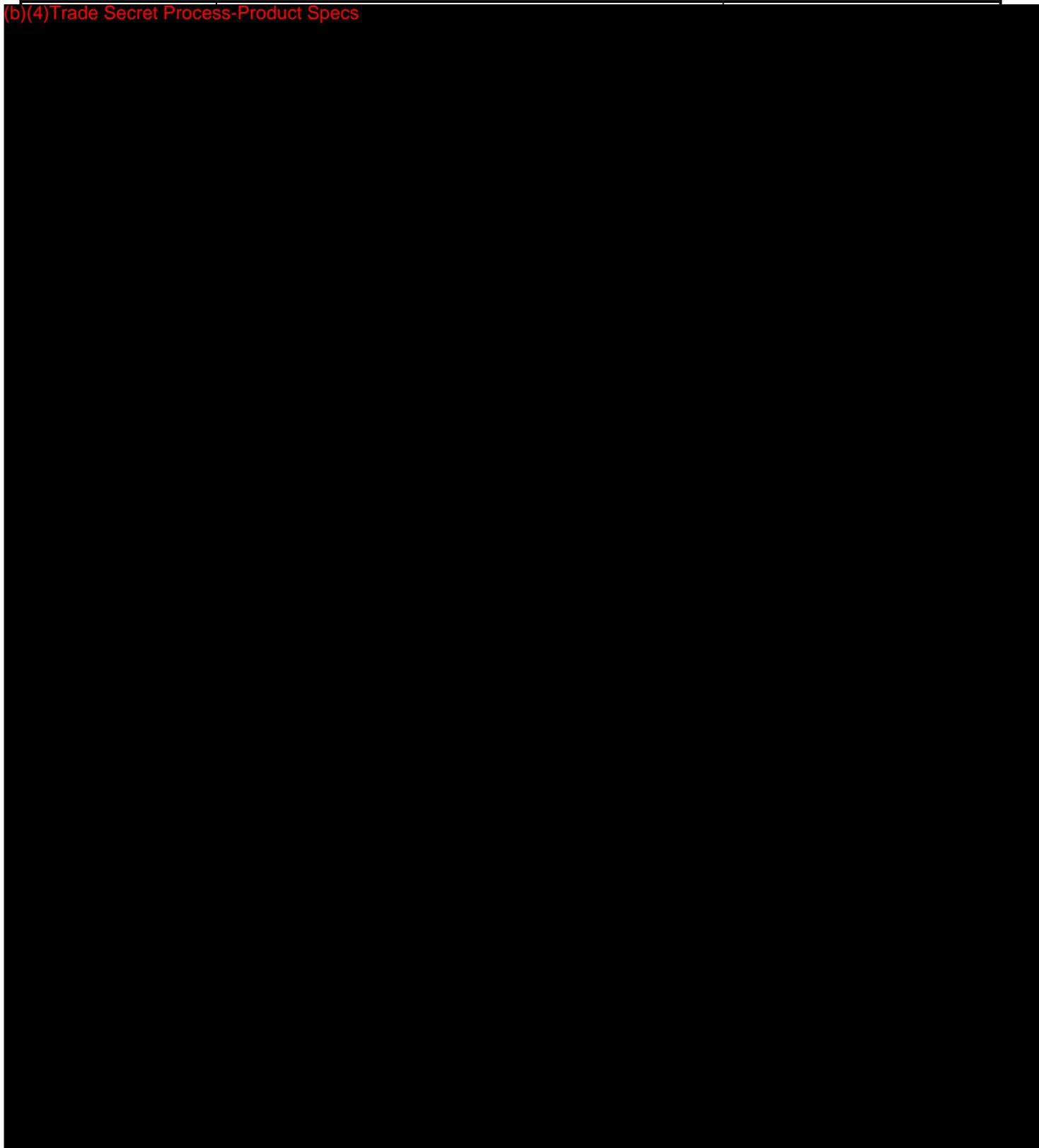
**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

AAMI/ANSI/ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity (2009)

CONFORMANCE WITH STANDARD SECTIONS*

(b)(4) Trade Secret Process-Product Specs



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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

EN ISO 10993-4 Biological evaluation of medical devices – Part 4: Selection of tests for interaction with blood (2009)
 VOLUNTARY

Please answer the following questions	Yes	No
Is this standard recognized by FDA ² ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
FDA Recognition number ³	N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were there exclusions from the standard? If yes, report these exclusions in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510(k)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Title of guidance: _____		

<p>¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p>² Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</p> <p>³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and</p>	<p>address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.</p> <p>⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁶ The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</p>
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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

EN ISO 10993-4 Biological evaluation of medical devices – Part 4: Selection of tests for interaction with blood (2009)
VOLUNTARY

CONFORMANCE WITH STANDARD SECTIONS*

(b)(4) Trade Secret Process-Product Specs

Department of Health and Human Services
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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI/ANSI/ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (2009)

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number ³ # 2-156

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
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Does this standard include more than one option or selection of tests?
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Were there exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: AAMI/ANSI/ISO 10993-12 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials (2007) and FDA Blue Book Memorandum G95-1 (1995)

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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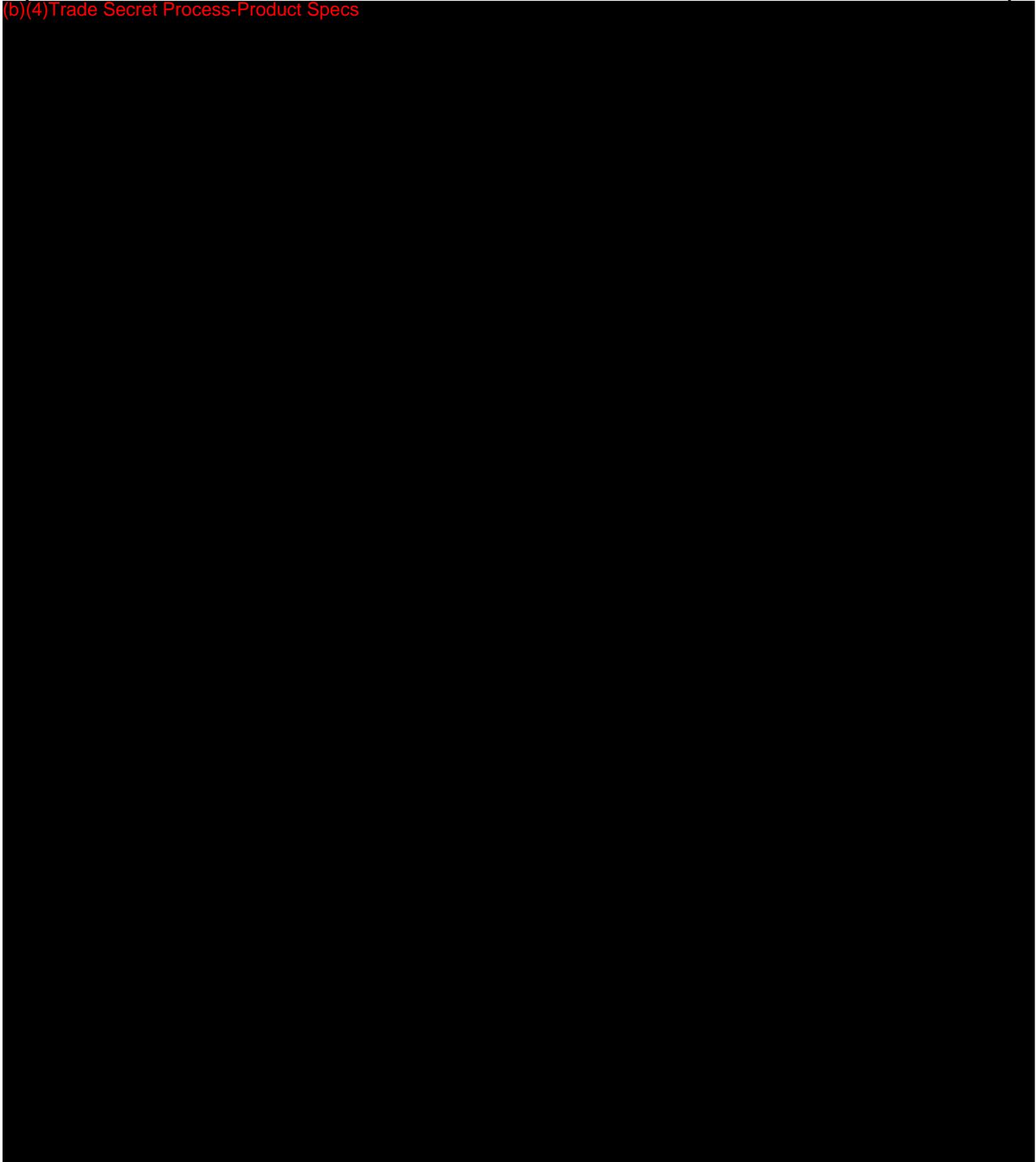
**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

AAMI/ANSI/ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (2009)

CONFORMANCE WITH STANDARD SECTIONS*

(b)(4) Trade Secret Process-Product Specs





26 Forest Street
Marlborough, MA 01752
Tel 508.658.7990

www.navilystmedical.com

C. Performance

The proposed NAMIC RCS conforms to the following FDA recognized standards:

- ISO 594-2:1998 – “Conical Fittings with 6% (Luer) Taper for Syringe, Needles, and Certain other Medical Equipment – Part 2: Lock Fittings”
- ISO 7886-1:1997 – “Sterile Hypodermic Syringes for Single Use, Syringes for Manual Use”

(b)(4)Trade Secret Process-Product Specs



Department of Health and Human Services
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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

BS EN ISO 7886-1:1997, Sterile Hypodermic Syringes for Single Use – Part 1: Syringes for Manual Use

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number ³ # 6-170

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

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Were there exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: Guidance on the Content of Pre-Market Notification [510(k)] Submissions for Piston Syringes – April 1993

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

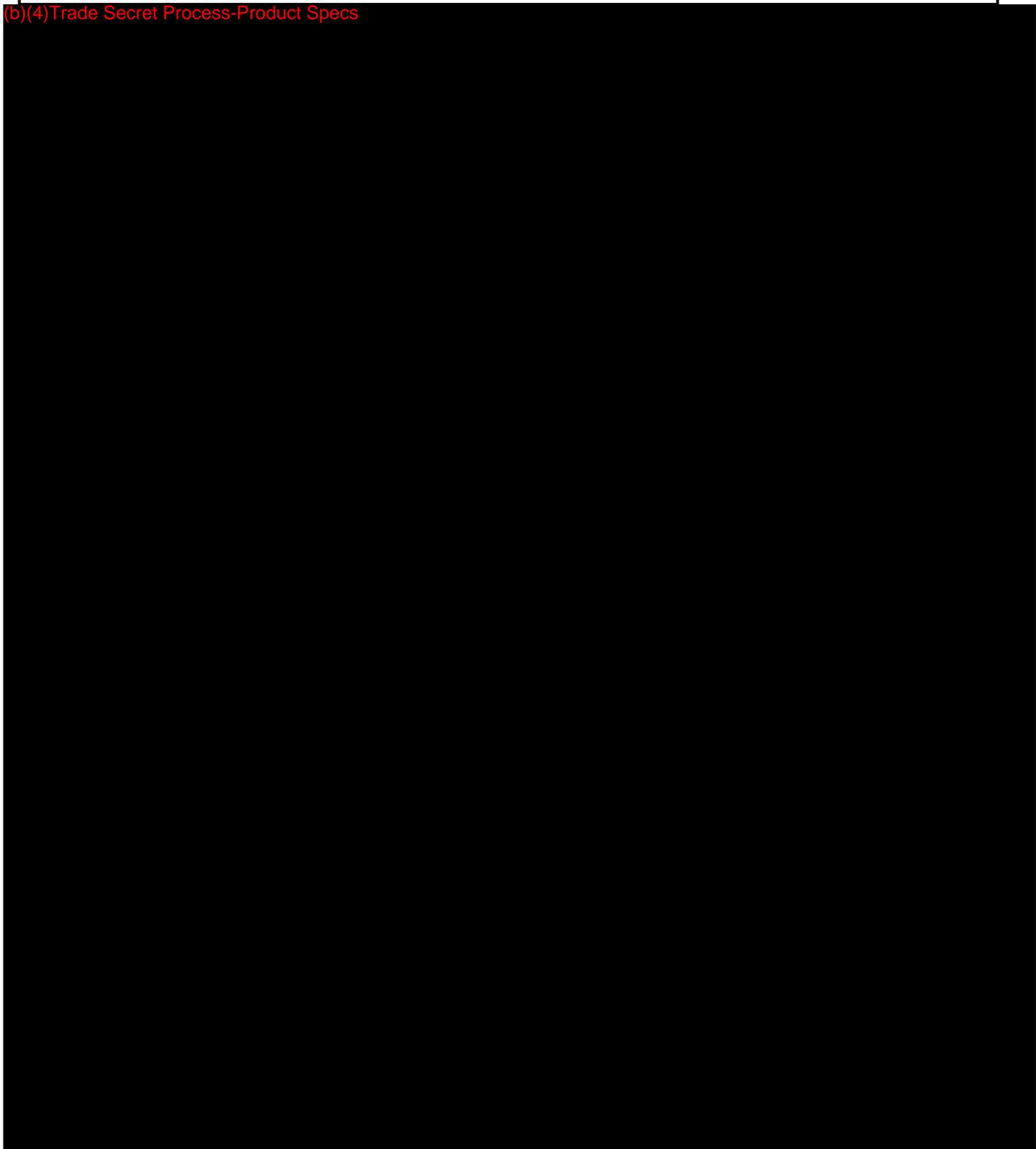
**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

BS EN ISO 7886-1:1997, Sterile Hypodermic Syringes for Single Use – Part 1: Syringes for Manual Use

CONFORMANCE WITH STANDARD SECTIONS*

(b)(4)Trade Secret Process-Product Specs



Department of Health and Human Services
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STANDARDS DATA REPORT FOR 510(k)s
 (To be filled in by applicant)

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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 594-2: Conical Fittings 6% (Luer) Taper for Syringes, Needles, Certain Medical Equipment – Part 2 (1998)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 6-129

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
 If yes, report these deviations or adaptations in the summary report table.

Were there exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: Submissions for Hypodermic Single Lumen Needles, Submissions for Piston Syringes, Sharps Injury

<p>¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p>² Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</p> <p>³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and</p>	<p>address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.</p> <p>⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁶ The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</p>
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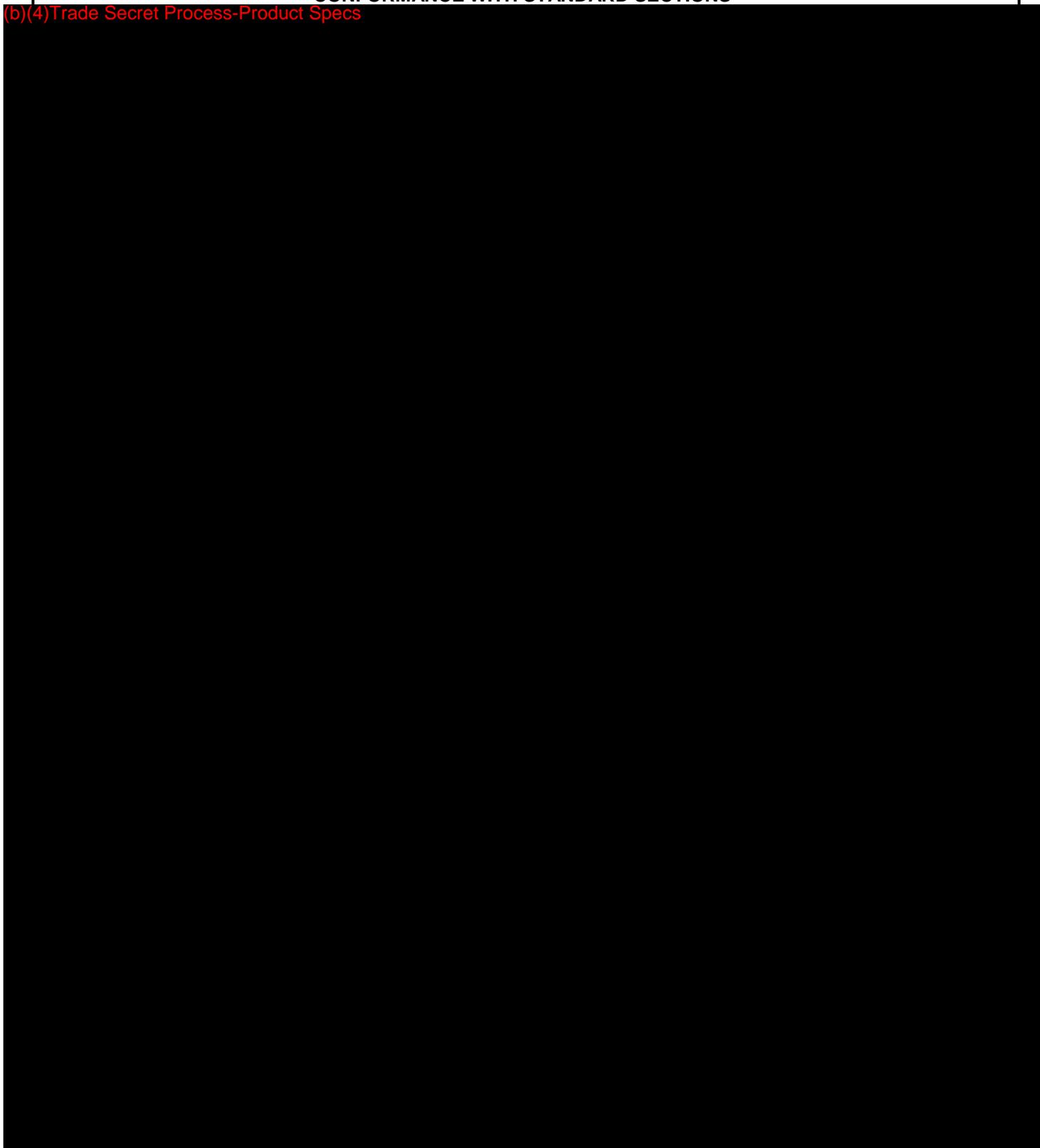
**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

ISO 594-2: Conical Fittings 6% (Luer) Taper for Syringes, Needles, Certain Medical Equipment – Part 2 (1998)

CONFORMANCE WITH STANDARD SECTIONS*

(b)(4) Trade Secret Process-Product Specs



D. Performance

The proposed NAMIC RCS conforms to the following FDA recognized standards:

- AAMI/ANSI/ISO 11607-1: 2006 – “Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems, 3rd Edition”
- AAMI/ANDI/ISO 11607-2: 2006 – “Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes, 1st Edition”
- ASTM F88/F88M:2009 – “Standard Test Method for Seal Strength of Flexible Barrier Materials”
- ASTM F1980:2007 – “Standard Guide for Accelerated Aging of Sterile Medical Device Packages”
- ASTM F1929-98:2004 – “Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration”
- ASTM F1886/F1886M:2009 – “Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection”

The proposed NAMIC RCS also conforms to the following voluntary standards:

- ISTA 2A:2011 – “Performance Test for Packaged-Products 150 lb (68kg) or Less”

(b)(4)Trade Secret Process-Product Specs



AAMI/ANSI/ISO 11607-1 Element

SECTION NUMBER 4.1	SECTION TITLE General Requirements	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED N/A		

(b)(4)Trade Secret Process-Product Specs

SECTION NUMBER 4.1	SECTION TITLE General Requirements	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED N/A		

(b)(4)Trade Secret Process-Product Specs

SECTION NUMBER 4.1	SECTION TITLE General Requirements	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED N/A		

(b)(4)Trade Secret Process-Product Specs

SECTION NUMBER 4.1	SECTION TITLE General Requirements	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED N/A		

(b)(4)Trade Secret Process-Product Specs

SECTION NUMBER 5.1.10	SECTION TITLE Materials & Preformed Sterile Barrier Systems - General Req's	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED N/A		

(b)(4)Trade Secret Process-Product Specs

SECTION NUMBER 5.1.11	SECTION TITLE Materials & Preformed Sterile Barrier Systems - General Req's	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED N/A		

(b)(4)Trade Secret Process-Product Specs

SECTION NUMBER 5.1.12	SECTION TITLE Materials & Preformed Sterile Barrier Systems - General Req's	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED N/A		

(b)(4)Trade Secret Process-Product Specs

SECTION NUMBER 6.2.4	SECTION TITLE Design	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED N/A		

(b)(4)Trade Secret Process-Product Specs

Department of Health and Human Services
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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISTA 2A Performance Test for Packaged-Products 150 lb (68kg) or Less (2011)

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number ³ # N/A _____

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
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Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

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If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
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Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

ISTA 2A Performance Test for Packaged-Products 150 lb (68kg) or Less (2011)

CONFORMANCE WITH STANDARD SECTIONS*

(b)(4) Trade Secret Process-Product Specs

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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI/ANSI/ISO 11607-2: 2006 Packaging for terminally sterilized medical devices-Part 2: Validation requirements for forming, sealing, and assembly processes ^{1^{ed}}

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number ³ # 14-194

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

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Were there exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: N/A

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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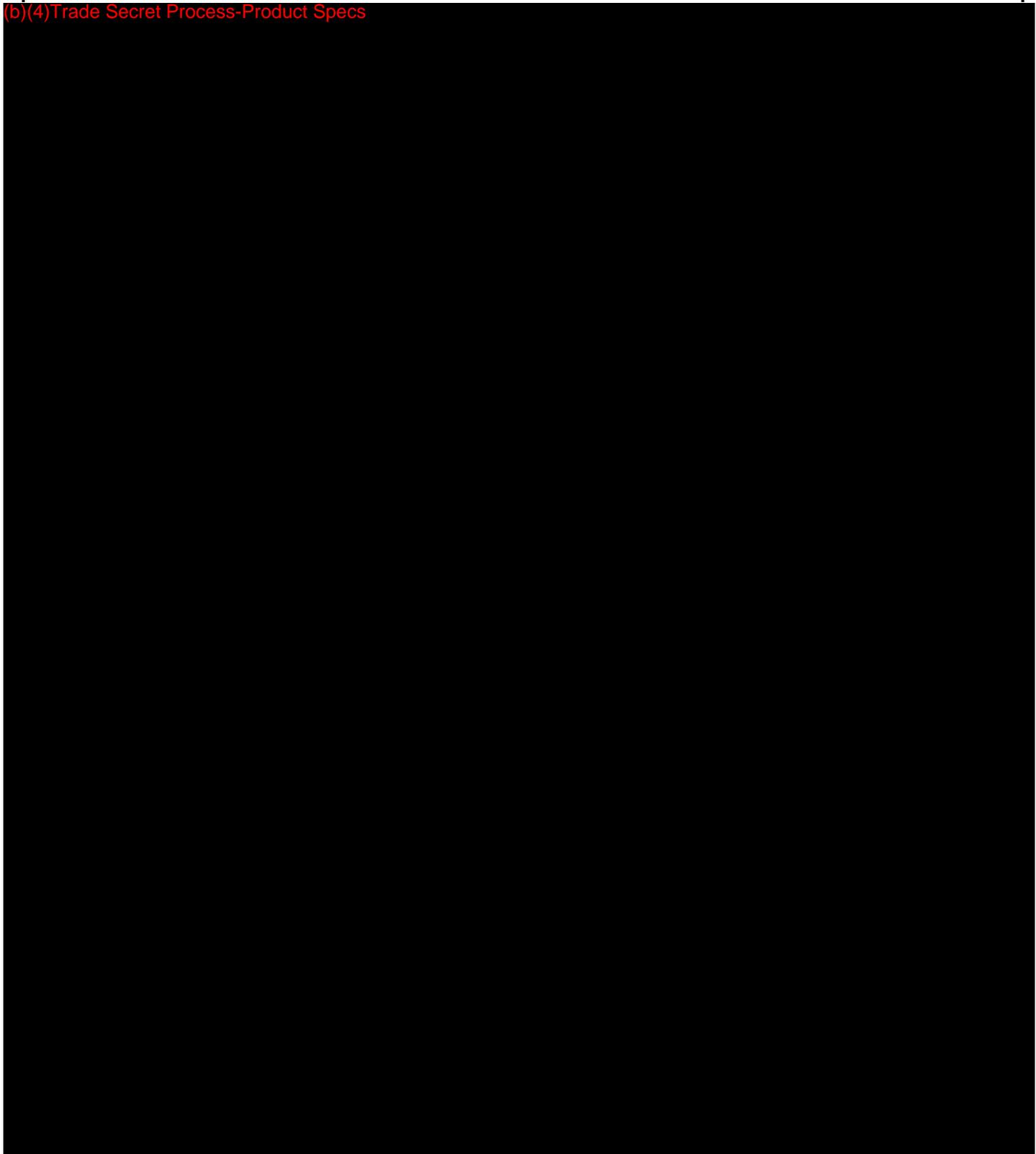
**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

AAMI/ANSI/ISO 11607-2: 2006 Packaging for terminally sterilized medical devices-Part 2: Validation requirements for forming, sealing, and assembly processes 1^{ed}

CONFORMANCE WITH STANDARD SECTIONS*

(b)(4) Trade Secret Process-Product Specs



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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI/ANSI/ISO 11607-1: 2006 Packaging for terminally sterilized medical devices-Part 1: Requirements for material, sterile barrier systems and packaging systems 3^{ed}

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number ³ # 14-193

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
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Were there exclusions from the standard?
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Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: N/A

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

AAMI/ANSI/ISO 11607-1: 2006 Packaging for terminally sterilized medical devices-Part 1: Requirements for material, sterile barrier systems and packaging systems 3^{ed}

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
See attachment	See attachment	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED^o

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

- * For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.
- * Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ASTM F 1980-07: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 14-229

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
 If yes, report these deviations or adaptations in the summary report table.

Were there exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: N/A

<p>¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p>² Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</p> <p>³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and</p>	<p>address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.</p> <p>⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁶ The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</p>
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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

ASTM F 1980-07: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All sections	All sections	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED[◇]
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ^{*}
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ^{*}
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

- * For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.
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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ASTM F 1929-98: Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration (2004)

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number ³ # 14-64

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
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Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
 If yes, report these deviations or adaptations in the summary report table.

Were there exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: N/A

<p>¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p>² Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</p> <p>³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and</p>	<p>address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.</p> <p>⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁶ The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</p>
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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

ASTM F 1929-98: Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration (2004)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All sections	All sections	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED[◇]
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ^{*}
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ^{*}
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

- * For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.
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Food and Drug Administration
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Department of Health and Human Services
 Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
 (To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ASTM F1886/F1886M-09: Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number ³ # 14-288

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
 If yes, report these deviations or adaptations in the summary report table.

Were there exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: N/A

<p>¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p>² Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</p> <p>³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and</p>	<p>address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.</p> <p>⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁶ The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</p>
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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

ASTM F1886/F1886M-09: Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All sections	All sections	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED◊
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

- * For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.
- * Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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TYPE OF 510(k) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ASTM F88/F88M-09: Standard Test Method for Seal Strength of Flexible Barrier Materials

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number ³ # 14-283

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

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 If yes, report these deviations or adaptations in the summary report table.

Were there exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: N/A

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

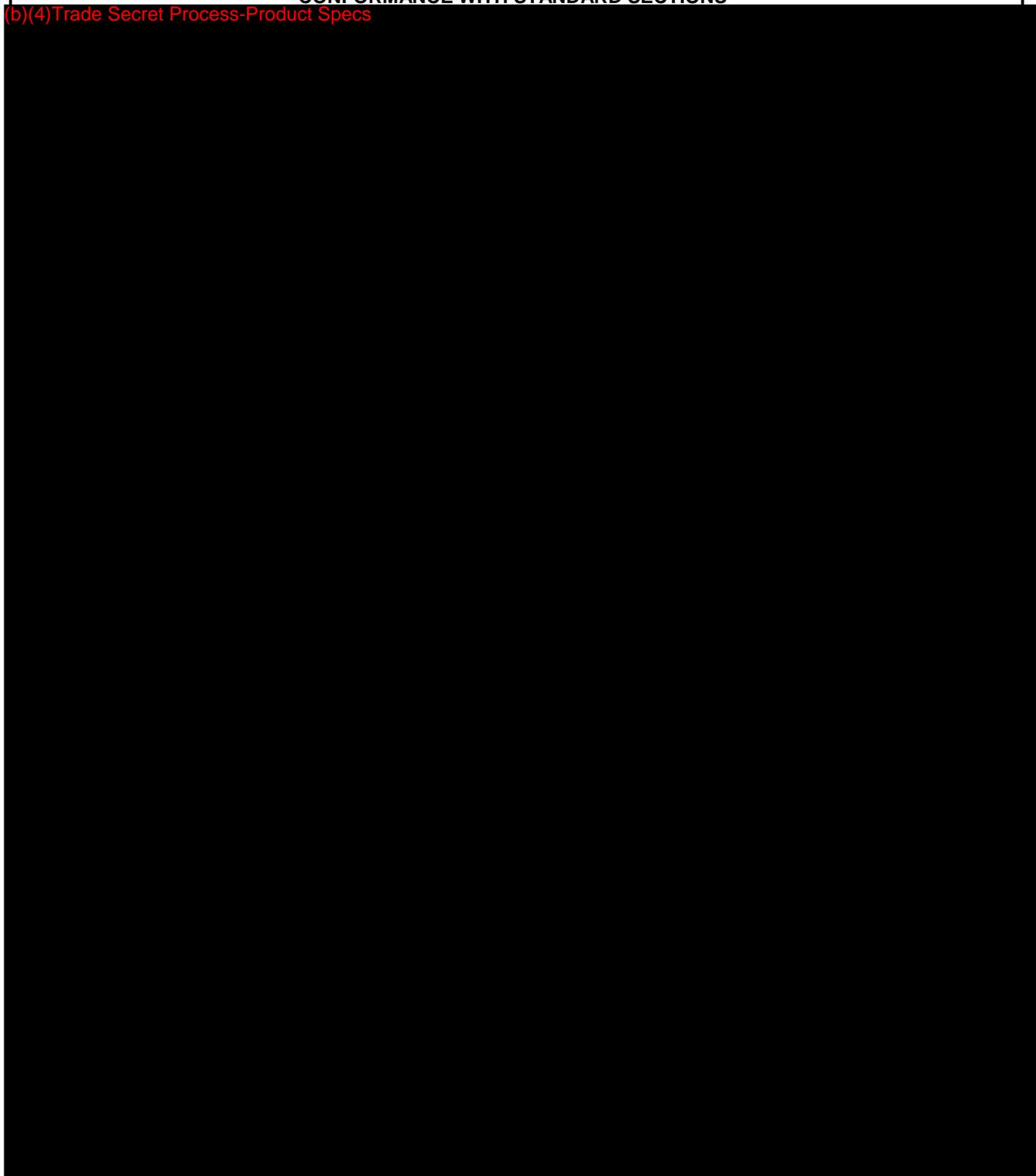
**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

ASTM F88/F88M-09: Standard Test Method for Seal Strength of Flexible Barrier Materials

CONFORMANCE WITH STANDARD SECTIONS*

(b)(4)Trade Secret Process-Product Specs



SECTION 19

CERTIFICATION OF COMPLIANCE WITH CLINICAL TRIALS

NO CLINICAL TRIALS were conducted in support of this submission.

Certification that the requirements of 42 U.S.C. 282(j)(5)(B) do not apply to this submission is provided in the attached FDA Form 3674.

SECTION 20

PROPOSED PROMOTIONAL LITERATURE

The proposed device does not have promotional literature.

ATTACHMENT 1

LABELING

Proposed Labeling:

- Draft NAMIC RCS Directions for Use
- Draft NAMIC RCS Product Labels

Predicate **K113198** Labeling

- Directions for Use
- Product Labels

Predicate **K875196** Labeling:

- Directions for Use
- Product Labels



NAMIC

Polycarbonate Syringe



2013-12

Rx ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Navilyst Medical representative. Inspect prior to use to verify that no damage has occurred during shipping.

For single patient use only. Do not reuse, reprocess or sterilize. Reuse, reprocessing or sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

Polycarbonate Syringe

The tolerance on any graduated capacity of the *NAMIC** Polycarbonate Syringe is as follows:

Nominal Capacity of Syringe	Less than Half Nominal Capacity	Equal to or Greater than Half Nominal Capacity
1, 3 mL	+/- (1.5% of Nominal Capacity +2% of Expelled Volume)	+/- 5% of Expelled Volume
6, 10, 20 mL	+/- (1.5% of Nominal Capacity + 1% of Expelled Volume)	+/- 4% of Expelled Volume

The *NAMIC* Polycarbonate Syringe is non-pyrogenic.

INTENDED USE/ INDICATIONS FOR USE

The *NAMIC* Polycarbonate Syringe is intended to be used for the intra-arterial or intra-venous administration of radiographic contrast media and saline solutions used during an angiographic procedure.

CONTRAINDICATIONS

None known.

WARNINGS

- Do not store fluid in device. Inject immediately after filling.
- Device does not contain a pressure gauge and it is not intended for the inflation of devices (i.e. balloons, stents, etc.)
- Finger tighten all connections and do not over tighten, as that may lead to cracks and/or leaks, which may result in exposure to biohazards, air embolism, and in rare instances death.
- User must inspect syringe for leaks and cracks, de-bubble syringe and confirm syringe does not contain air bubbles prior to use, to minimize the potential for air embolism and in rare instances death.

POSSIBLE COMPLICATIONS/ADVERSE EVENTS

Potential complications associated with the use of *NAMIC* Polycarbonate Syringes include, but not limited to the following:

- Air embolism
- Allergic reaction (including anaphylaxis)
- Arterial/venous thrombosis
- Cardiac or respiratory arrest
- Cerebral vascular accident
- Death
- Exposure to biohazards
- Hemorrhage
- Infection
- Myocardial infarction
- Transient ischemic attack (TIA)

HOW SUPPLIED

Contents supplied STERILE using an ethylene oxide (EO) process. Store in a cool, dry, dark place. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

WARRANTY

Navilyst Medical, Inc. warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Navilyst Medical's control directly affect the instrument and the results obtained from its use. Navilyst Medical's obligation under this warranty is limited to the repair or replacement of this instrument and Navilyst Medical shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. Navilyst Medical neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **Navilyst Medical assumes no liability with respect to instruments reused, reprocessed, resterilized, modified or altered in any way, and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

* Navilyst and *NAMIC* are trademarks and/or registered trademarks of AngioDynamics, Inc. and affiliate or a subsidiary.

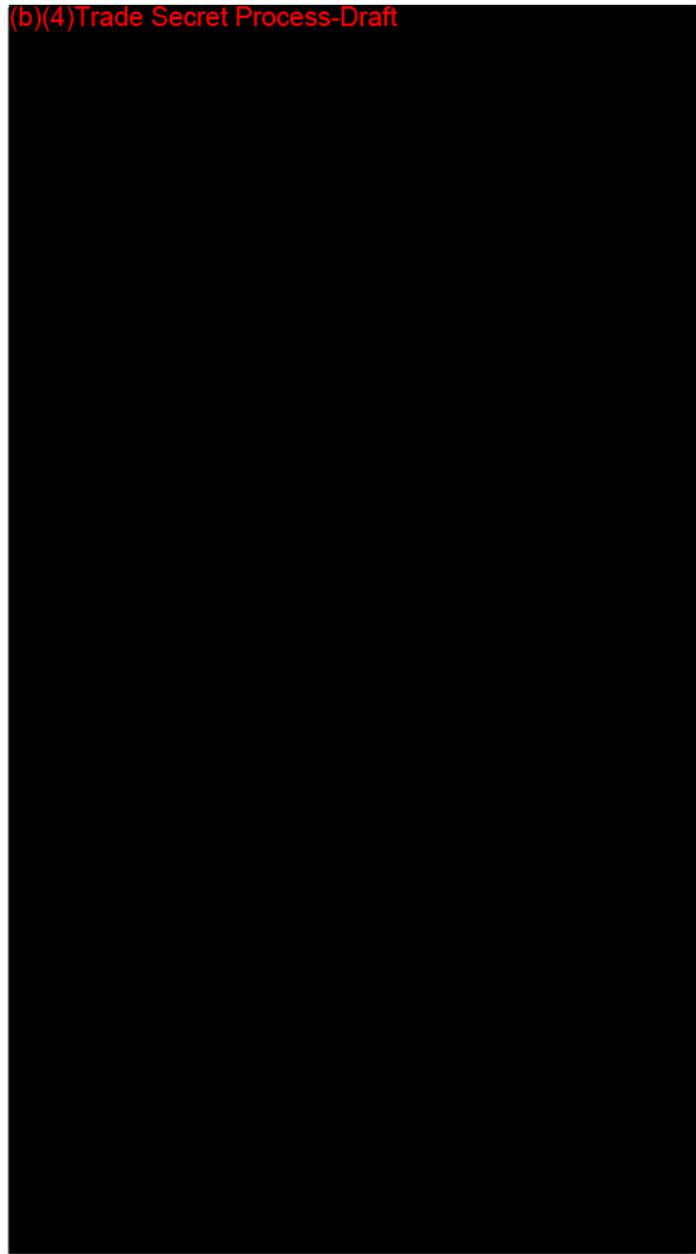
Legal Manufacturer

Navilyst Medical, Inc.
26 Forest Street
Marlborough, MA 01752 USA
Kundtjänst USA 800-833-9973

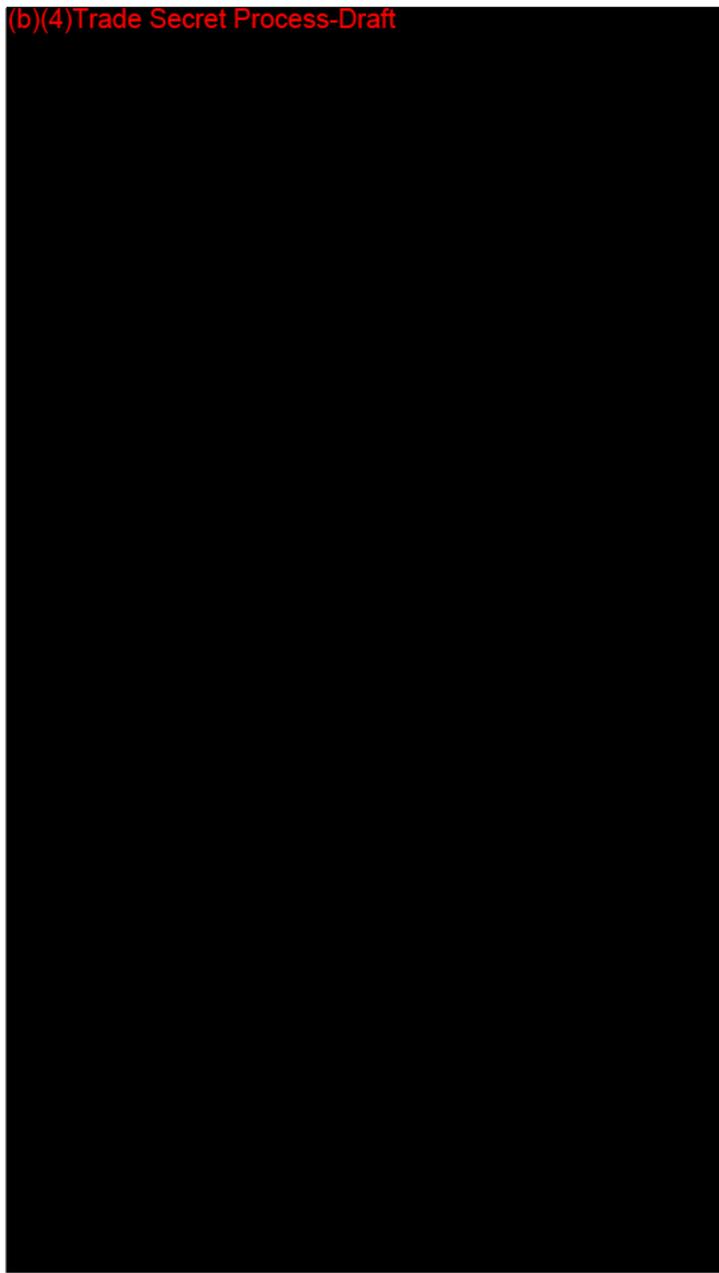


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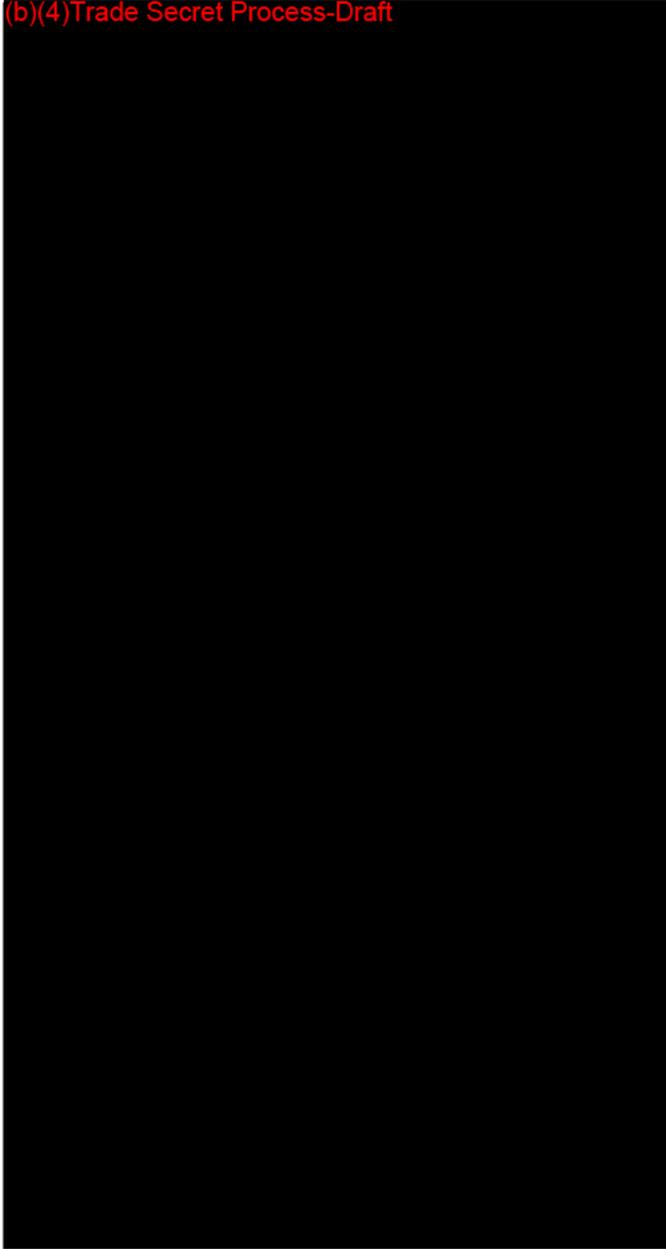
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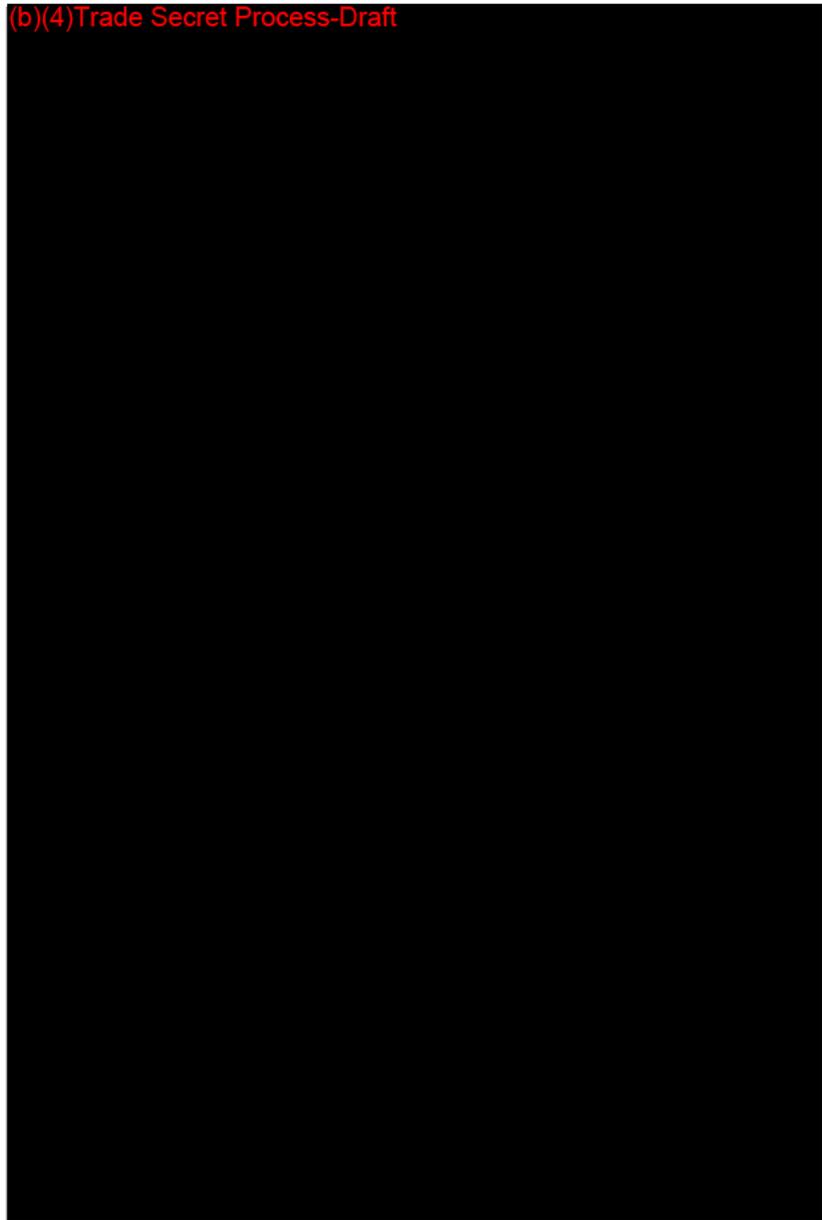
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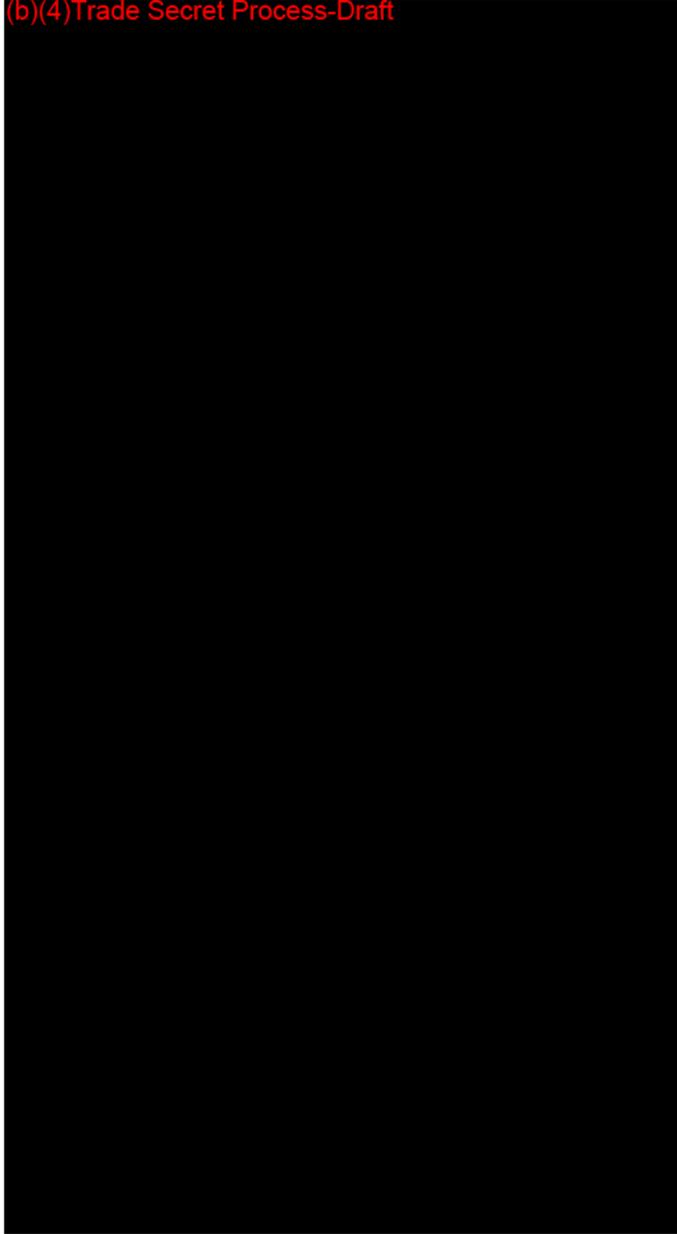
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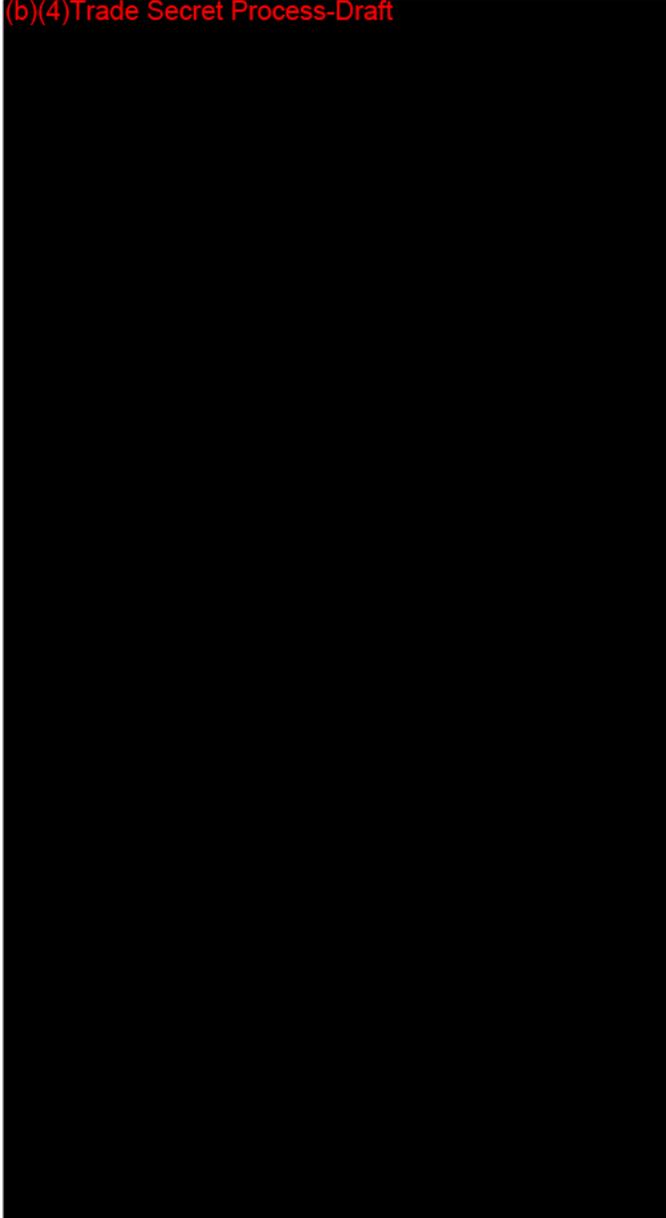
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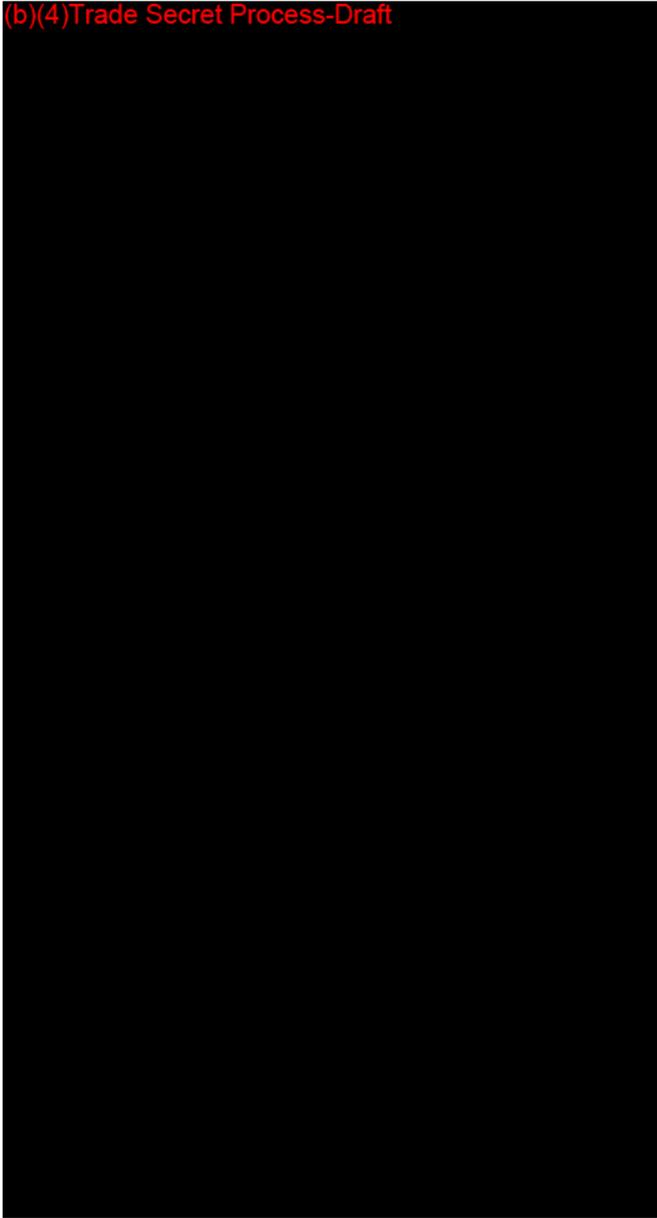
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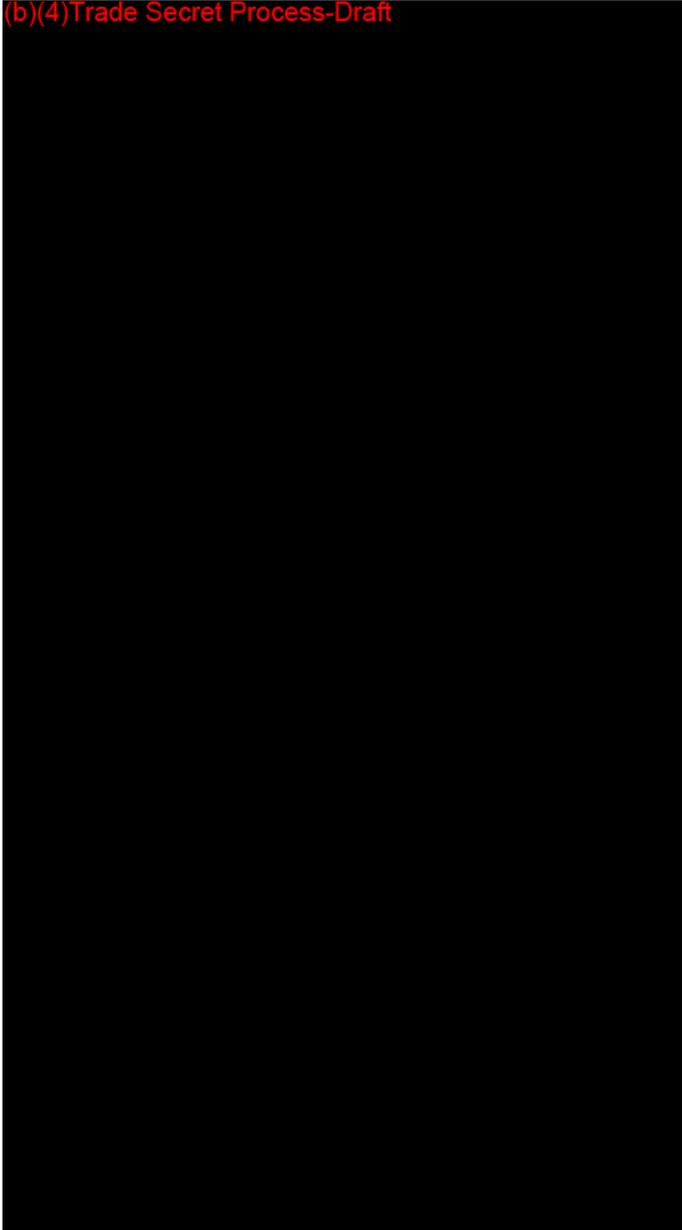
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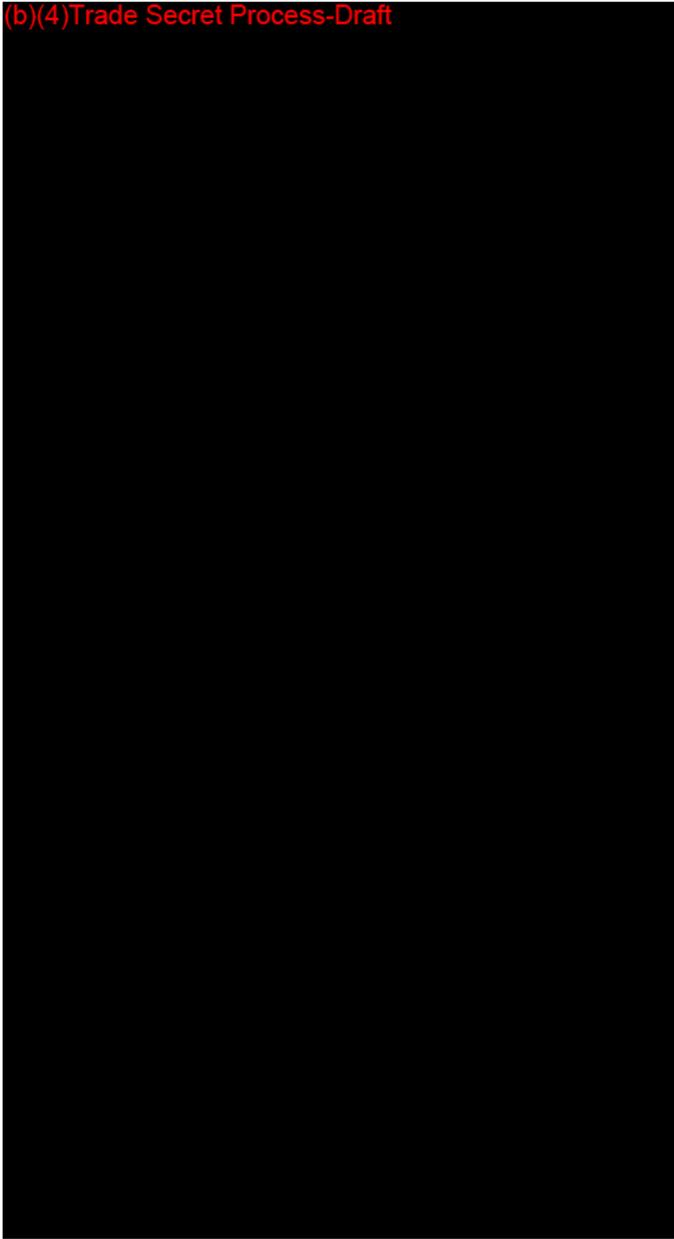
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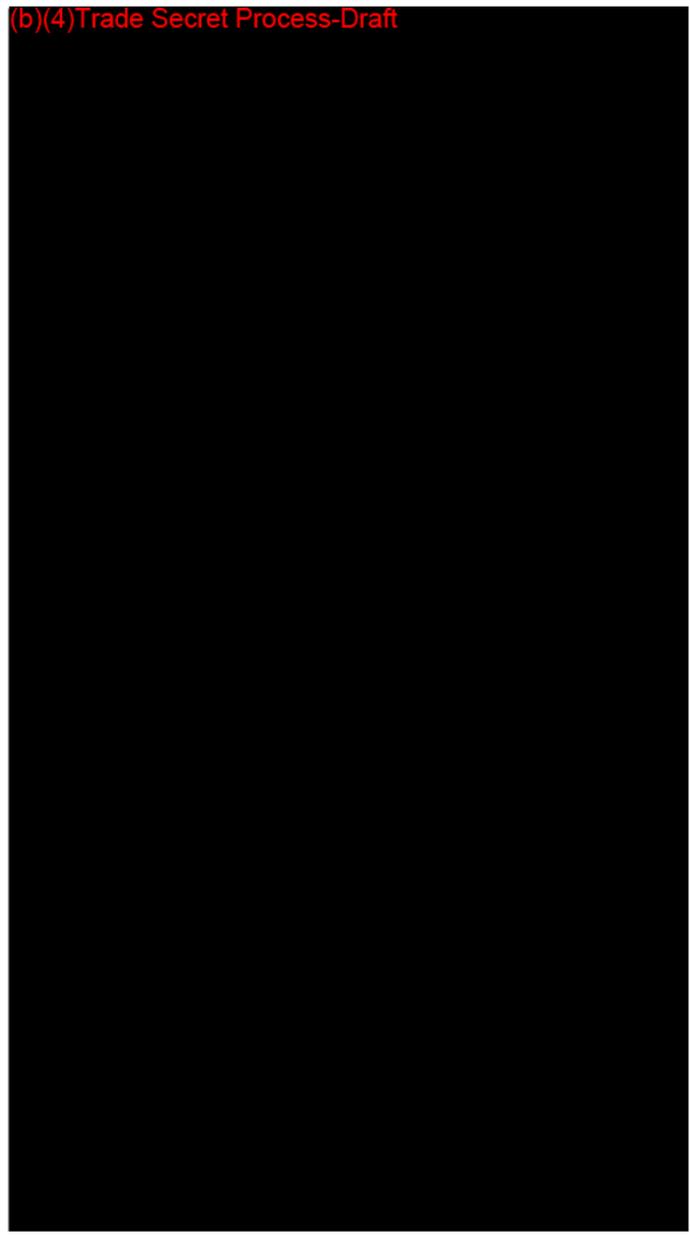
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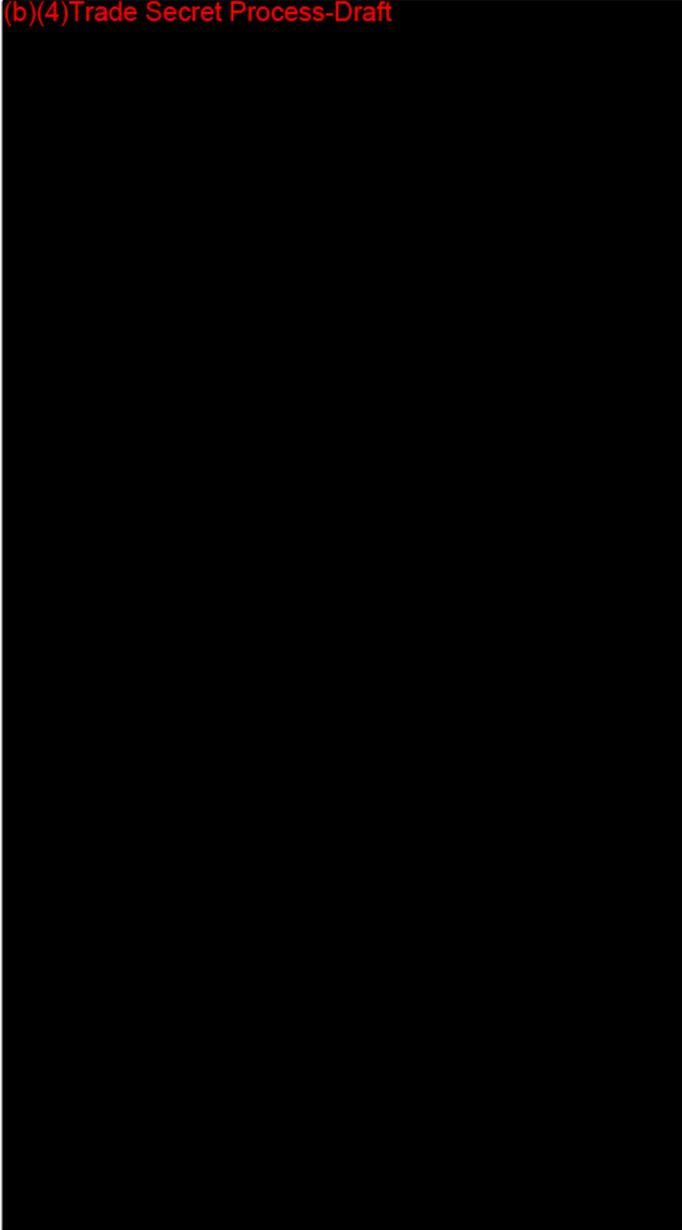
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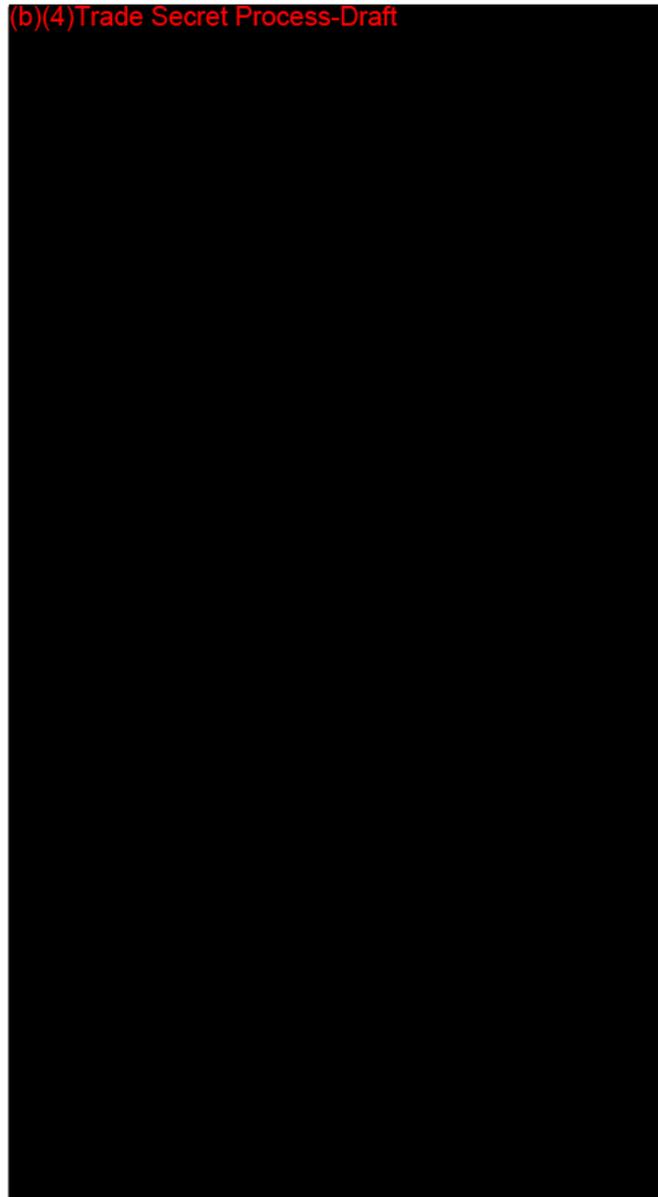
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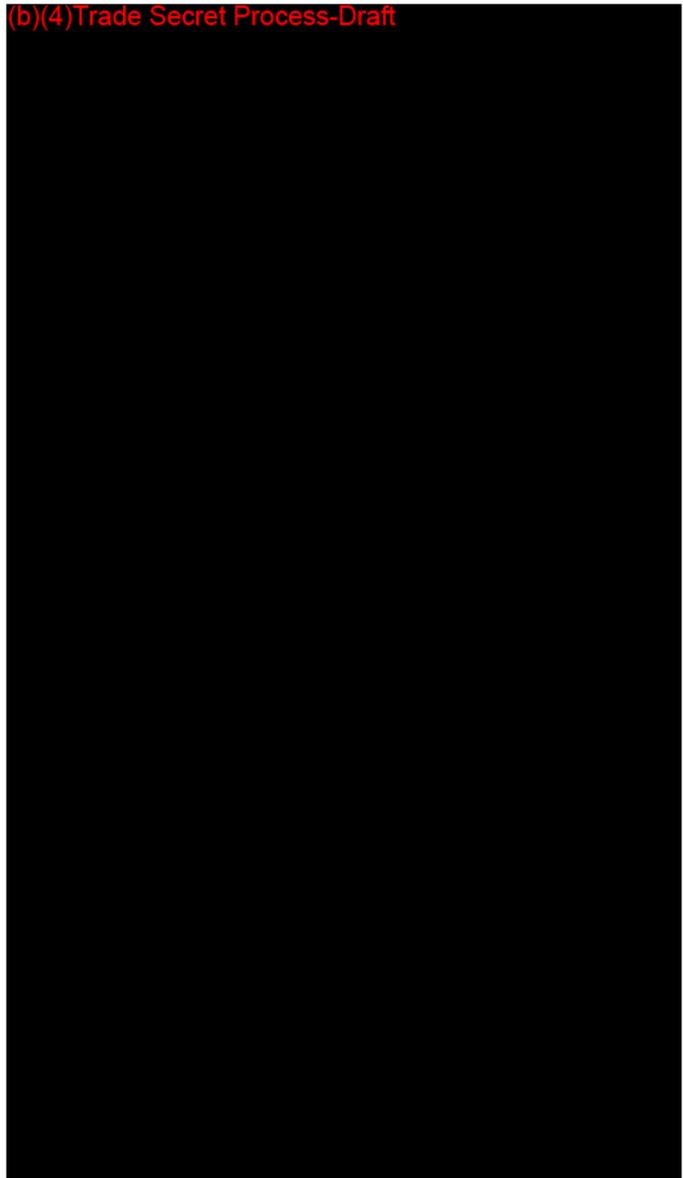
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(b)(4) Trade Secret Process-Draft



(b)(4) Trade Secret Process-Draft



(b)(4)Trade Secret Process-Draft





Navilyst
Medical

NAMIC™

Angiographic **Control Syringe**

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16650001-01
2011-04

A

Navilyst Medical, Master DFU Template Z7 in x 9 In Global, 14672709 Rev1/Ver. A; DFU, ANGIOGRAPHIC CONTROL SYRINGE, 16650001-01A

Rx ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Navilyst Medical representative. Inspect prior to use to verify that no damage has occurred during shipping.

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

Angiographic Control Syringe

The tolerance on any graduated capacity of the NAMIC™ Angiographic Control Syringe is as follows:

- Less than half nominal capacity: \pm (1.5% of nominal capacity + 1% of expelled volume)
- Equal to or greater than half nominal capacity: \pm 4% of expelled volume

The NAMIC Angiographic Control Syringe is compatible with the radiographic contrast media and 0.9% sodium chloride solution used in angiographic procedures.

INTENDED USE/ INDICATIONS FOR USE

The NAMIC Angiographic Control Syringe is intended to be used for the intra-arterial or intravenous administration of radiographic contrast media.

CONTRAINDICATIONS

None known.

WARNINGS

- Do not store fluid in product. Inject immediately after filling.
- This syringe does not have a pressure gauge device. Therefore, it is not intended for balloon catheter inflation. Over inflation may result in the rupturing of the balloon.
- Ensure that you are making secure connections when using this device to prevent the introduction of air into the system that could result in embolism and in rare instances death.
- All connections should be finger tightened. Over tightening can cause cracks and leaks to occur that could result in embolism and or exposure to biohazards.
- Verify that there is not leakage by aspirating and checking to see that air is not trapped in the system to minimize the potential for embolism and in rare instances death.
- Examine product carefully for entrapped air and fully debubble prior to injection to minimize the potential for embolism and in rare instances death.

PRECAUTIONS

- None known

POTENTIAL COMPLICATIONS

Potential complications associated with the use of Angiographic Control Syringes include, but not limited to the following:

- | | |
|---|-----------------------------------|
| • Allergic reaction (including anaphylaxis) | • Exposure to biohazards |
| • Arterial/venous thrombosis | • Hemorrhage |
| • Cardiac or respiratory arrest | • Infection |
| • Cerebral vascular accident | • Myocardial infarction |
| • Death | • Transient ischemic attack (TIA) |
| • Embolism | |

HOW SUPPLIED

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WARRANTY

Navilyst Medical, Inc. warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Navilyst Medical's control directly affect the instrument and the results obtained from its use. Navilyst Medical's obligation under this warranty is limited to the repair or replacement of this instrument and Navilyst Medical shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. Navilyst Medical neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. Navilyst Medical assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.

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GARANTIE

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GARANTIE

Navilyst Medical, Inc., garantiert, dass bei der Konstruktion und Herstellung dieses Instruments mit angemessener Sorgfalt vorgegangen wurde. Diese Garantie ersetzt alle anderen ausdrücklichen oder stillschweigenden gesetzlichen oder anderweitig implizierten Garantien, die hier nicht ausdrücklich erwähnt werden, und schließt diese aus, einschließlich, aber nicht beschränkt auf jegliche implizierten Zusicherungen in Bezug auf marktgängige Qualität oder Eignung für einen bestimmten Zweck. Die Handhabung, Aufbewahrung, Reinigung und Sterilisierung dieses Instruments sowie andere Faktoren, die sich auf den Patienten, die Diagnose, die Behandlung, chirurgische Verfahren und andere Umstände beziehen, die außerhalb der Kontrolle von Navilyst Medical liegen, haben direkten Einfluss auf das Instrument und die Resultate aus seinem Einsatz. Die Verpflichtung von Navilyst Medical im Rahmen dieser Garantie beschränkt sich auf die Reparatur oder den Ersatz des betreffenden Instruments; Navilyst Medical ist nicht haltbar für beiläufige bzw. Folgeverluste, Schäden oder Kosten, die sich direkt oder indirekt aus der Verwendung dieses Instruments ergeben. Navilyst Medical beauftragt bzw. autorisiert auch Dritte nicht, weitere Haftungsverpflichtungen bzw. Verantwortung in Verbindung mit dieser Vorrichtung für sie selbst oder andere Firmen zu übernehmen. Navilyst Medical übernimmt keine Haftung für wieder verwendete, wieder aufbereitete oder reesterilisierte Instrumente, weder ausdrücklich noch stillschweigend, einschließlich, aber nicht beschränkt auf, ihre marktgängige Qualität oder ihre Eignung für einen bestimmten Zweck.

Navilyst Medical, Inc.
NAMIC RCS, Abbreviated 510(k)
January 24, 2014

ATTACHMENT 2

BIOCOMPATIBILITY REPORTS (CONTAINING PROTOCOL)

EXPERIMENTAL DESIGN

Experimental Summary

Animals were treated by intravenous or intraperitoneal routes to screen solutions or test article extracts for potential toxic effects as a result of a single-dose systemic injection. The animal species, number, and route of test article administration were as recommended in ISO 10993-11.

For the safety evaluation of the test article, mice were injected systemically with extracts of the test article in standard solutions (normal saline and sesame oil). The animals were observed for signs of toxicity immediately after injection and at 4, 24, 48, and 72 hours post-injection. The requirements of the test are met if none of the animals treated with the test article extract have a significantly greater adverse reaction than the animals treated with the vehicle control.

Justification for Selection of the Test System

Mice were used in this study because they have historically been used in systemic safety evaluation studies and the guidelines have no alternative (non-animal) methods. Animals were treated by intravenous and intraperitoneal routes. The animal species, number, and route of test article administration were as recommended in ISO 10993-11.

Institutional Animal Care and Use Committee (IACUC)

The protocol and any amendments or procedures involving the care or use of animals on this study were reviewed and approved by the WuXi AppTec IACUC prior to the initiation of such procedures.

IACUC Protocol / Effective Date: 98-03F / June, 2013

PROTOCOL AMENDMENTS/DEVIATIONS

There were no amendments or deviations that occurred during the course of this study.

IDENTIFICATION OF TEST SYSTEM

Species/Strain: All animals used in this study were albino Swiss mice (*Mus musculus*), CFW, naïve.

Source: Animals were obtained from Charles River Laboratories, a previously approved vendor of commercial laboratory animals.

Sex: All of the animals used were female, nulliparous and non-pregnant.

Weight Range: All animal weights (21.9-27.8 grams) were within $\pm 20\%$ of the mean body weight at the start of the study.

Age: All animals were 6 weeks old at the start of the study.

Number: The study used 10 mice/ extract vehicle (5 test, 5 control).

Animal Identification: The animals were identified per WuXi AppTec SOP: ILS-0112.

Animal Numbers:	Mouse #
0.9% Normal Saline Test Group:	1 - 5
0.9% Normal Saline Control Group:	21 - 25
Sesame Oil Test Group:	11 - 15
Sesame Oil Control Group:	31 - 35

